EXHIBIT 13

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
COLUMBUS DIVISION

MDL Case No. 2004

IN RE: MENTOR CORP. OBTAPE TRANSOBTURATOR SLING PRODUCTS LIABILITY LITIGATION

DEPOSITION OF
DANIEL S. ELLIOTT, M.D.

Taken on July 24, 2016

Commencing at 8:44 a.m.

Job No. CS2350044

REPORTED BY: PAULA K. RICHTER, RMR, CRR

DEPOSITION OF DANIEL S. ELLIOTT, M.D., taken on July 24, 2016, commencing at 8:44 a.m., at the Marquette Hotel, 710 South Marquette Avenue, Canon River Room, Third Floor, Minneapolis, MN 55402, before Paula K. Richter, Registered Merit Reporter, Certified Realtime Reporter, and Notary Public of and for the State of Minnesota.

****

APPEARANCES

On Behalf of Plaintiff Andrea R. Clinton:

Mr. Douglass A. Kreis, Esq.
AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC
17 East Main Street, Suite 200
Pensacola, FL 32502
(850) 202-1010
dkreis@awkolaw.com

(APPEARANCES continued on next page)

APPEARANCES (Continued)

On Behalf of Defendant Mentor Worldwide, LLC:

Mr. John Q. Lewis, Esq.
TUCKER ELLIS, LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113
(216) 592-5000
john.lewis@tuckerellis.com

NOTE: The original transcript will be filed with TUCKER ELLIS, LLP, pursuant to the applicable Rules of Civil Procedure.

INDEX

(EXHIBITS continued on next page)

(Original exhibits attached to original transcript; copies attached to transcript copies.)

PROCEEDINGS

DANIEL S. ELLIOTT, M.D.

duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. LEWIS:

Q. Good morning, Doctor. How are you?

A. Good morning.

Q. We met off the record. My name is John Lewis. I represent Mentor in a case that's been brought by Andrea Clinton related to her experience with ObTape transobturator tape.

You've been designated by Ms. Clinton's attorneys as an expert in this litigation. Do you have an understanding as to that.

A. Correct. That's true.

Q. And could you for the record just let the court reporter know your full name and your current business address, please?

A. Dr. Daniel Steven Elliott, S-T-E-V-E-N, last name Elliott, E-L-L-I-O-T-T. Address is 200 First Street Southwest, Rochester, Minnesota.

Q. And, Doctor, do you have an understanding

that you're going to be testifying at the trial in this case set for January of next year?

A. Correct.

Q. All right. And do you plan to appear live for that?

A. Yes.

(Exhibit 1 was marked for identification.)

BY MR. LEWIS:

Q. I'm going to show you, just to get a couple things out of the way. This is Deposition Exhibit 1. Do you have an understanding that there was a deposition notice issued in this case?

A. Yes.

Q. And you're appearing subject to that notice; is that right?

A. Correct.

Q. Do you see that that's requested that you bring documents to the deposition?

A. Correct.

Q. And have you brought any documents today?

A. I have a copy of my reports, the general and then the case-specific report, and that's what I have with me.

Q. And as I understand it, there are some

billing records that can be obtained. You don't have those with you, but you are prepared to testify as to an estimate of your billings in this case?

A. Correct.

Q. And who has the billing records? Your office?

A. Well, no, not my office. It would be probably with Mr. Ben Anderson's law firm in Cleveland, Ohio.

Q. All right. I'll swing by on my way home.

(Exhibit 2 and Exhibit 3 were marked for identification.)

BY MR. LEWIS:

Q. So I have two reports of yours that I've marked here as Exhibits 2 and 3. I'm going to show those to you. Exhibit --

MR. KREIS: John, we sent over a supplemental reliance to I think Dustin on Friday. Did you have an opportunity to print that out?

MR. LEWIS: I did not.

MR. KREIS: I've got a copy that I can provide you today.

MR. LEWIS: Okay.

MR. KREIS: I can also e-mail it to

you.

MR. LEWIS: Okay. I mean, do you have it with you right now?

MR. KREIS: It's in here somewhere.

MR. LEWIS: Did you e-mail it to Dustin on Friday?

MR. KREIS: Yes.

BY MR. LEWIS:

Q. Doctor, Exhibit 2 is what I'll refer to as your general report in the ObTape litigation; is that correct?

A. Yes.

Q. And Exhibit 3 is the report specific to Ms. Clinton; is that correct?

A. Correct.

Q. And other than a supplemental reliance list, are there any changes to the reports, Exhibits 2 and 3, that you need to make regarding your opinions in this case as we sit here today?

A. There's nothing substantial. I found a couple typographical grammatic errors but nothing that change an opinion.

Q. And do you intend to do any additional work in this case -- in Ms. Clinton's case such that it would change or you expect that it would change

your opinions?
A. Only if new material were brought to me. I last saw her in, was it July 15 -- 25th of last year. So if new records were presented to me, that would obviously change, but I'm not anticipating searching those out unless something is brought to me.
Q. And do you have plans to perform any physical examinations or otherwise meet with Ms. Clinton prior to trial?
A. I have no plans unless her medical situation were to change. But otherwise, I have no plans to do that, no.
Q. No current plans at this time?
A. Correct.
Q. Now, let me ask you a little bit about the July 2015 encounter. Was that the only time that you met with Ms. Clinton in person?
A. Correct.
Q. And could you explain to me the circumstances under which you met with Ms. Clinton?
A. I had been contacted, I believe, by the AWKO Law Office to review records or to determine whether or not I felt individuals were harmed by Mentor. So I reviewed multiple records, including

Ms. Clinton. I then informed them that I felt that there were injuries caused by the product, and then at that point in time an IME was -- an independent medical exam was set up, a date and location.
Q. And how was the IME set up?
A. I don't know how that was done. I just told them I felt these certain number of individuals that I'd reviewed, there were problems associated -- or caused by the Mentor product, and then I told them dates that I was available and then it was set up in Chicago.
Q. So the independent medical exam took place in Chicago?
A. Correct.
Q. Where?
A. At Rush Medical Center.
Q. And how did you get access to Rush Medical Center facilities?
A. They told me a date and time to show up. I showed up and I walked up to the exam room -- or the office -- medical office.
Q. "They" meaning the -- Ms. Clinton's lawyers?
A. No, no. I never encountered any lawyers. I don't know who represents them. No. It was the

nurse who works at that medical facility.
Q. I'm sorry. Okay. So the nurse at Rush Medical Center contacted you and gave you the time and place to go for the examination?
A. No. The AWKO Law Office said, okay, 8:00 a.m. on July 25th, show up at this address. They will let you in. "They" meaning the employee of the Rush -- actually, I don't even know who the employee was. It's a nurse who works there, so I don't know her direct employ is. So I had no contact with any lawyers or any other individuals besides just Ms. Clinton.
Q. I mean, other than her lawyers -- other than Ms. Clinton's lawyers --
A. No.
Q. -- to set up the appointment?
A. Yes. But I didn't have any contact on the IME day with anybody legal, let's put it that way. Just Ms. Clinton and then the nurse.
Q. Okay. And why was Chicago chosen?
A. I don't know.
Q. Do you practice medicine in Chicago --
A. No.
Q. -- or Illinois?
A. No.

Q. Did you need to get special permission to conduct the examination in Illinois?
A. No.
Q. Have you ever used the facilities at Rush Medical Center prior to or since that examination?
A. I don't recall since then. Prior to that time, several IMEs have been set up for various different products, mainly the Ethicon products, at that facility. I believe Chicago was chosen because it was semi centrally located, somewhat easy to get into, but other than that, I don't know.
Q. So you've performed other independent medical examinations in the context of litigation and have used Rush Medical Center for the place for the examination?
A. Used that specific office and only that one office.
Q. And when you say "specific office", could you describe it for me? Is it an office that is set aside for physicians who do IMEs in litigation?
A. I have no idea. It appeared to be a GYN office because they're fully stocked with GYN equipment. On the walls they had OB and GYN paraphernalia, as far as literature information,

but I don't know whose office it is or why that one was chosen.
Q. And you don't remember seeing a name outside the office indicating whose office it was?
A. No, no. Just -- no, I did not.
Q. Okay. In advance of the independent medical exam of Ms. Clinton, did you need to request that certain things be present or did you bring your own examination equipment?
A. No. I just request that we have a vaginal -- disposable vaginal speculums available, and that was the only equipment needed.
Q. How many IMEs do you think you've done in litigation for mesh products?
A. For all of mesh products? That would include, you know, Prolift, TVT, TVT-O, TVT-Secur, Avaulta, Cook and this, so there's probably -- I'm going to have to guess. It's going to be a rough guess. 75 perhaps. But please take that with a grain of salt. That's a rough guess over the past five years.
Q. Totally understand.
You listed some products there. I just -- so a volume at that is a product that you've testified in litigation regarding?

A. I performed IMEs, wrote up a report -- a general report and then case specifics. I gave testimony two years, three years ago perhaps, and I've heard nothing since then. And I believe that's a Bard product, but I'm not sure on that one.
Q. So Avaulta is one. Another one is TVT-O?
A. All the TVT line. The TVT-O, TVT-Secur, and the TVT Classic or Retropubic.
Q. Call it Classic or Retropubic?
A. Retropubic is what I meant.
Q. Yeah. And those are made by Ethicon, correct?
A. Correct.
Q. What other products have you testified in litigation or otherwise performed examinations for litigation?
A. The Prolift line, so anterior, posterior and total, but that would all fall under the umbrella of Prolift, correct.
Q. And that was Ethicon, correct?
A. Correct.
Q. Others?
A. The Cook product line, which is an SIS.
Q. SIS?

A. SIS is sub-intestinal mucosa, I believe. It is not a synthetic mesh. It is taken from pig intestines and used as a prolapse or a sling material for anti-incontinence.
Q. So SIS is a -- I'm sorry, what --
A. Cook Medical, based in Indiana.
Q. Okay. Other products? I mean, ObTape, obviously.
A. ObTape, yes.
Off the top of my head, I do not recall there being another one.
Q. Any AMS products?
A. No. I've been contacted about doing something but nothing has ever come about. I've not done any reviews, no reports or any depositions on that. Same thing with Coloplast.
Q. And Boston Scientific, nothing there?
A. Nothing there.
Q. So you performed an examination in July of 2015. Did you take notes at that examination?
A. I have a pre-printed form that covers -- and this would be my standard routine -- all aspects of a female genital urinary exam. Then as I examine her, take pencil notes on that, clarify it with her, and then that day or the next day, put

that all into a Word document. The original chicken scratch, pencil forms, are shredded because all that data goes into this report which you have before you.
Q. And so the form that was used for Ms. Clinton's examination, that is no longer available; is that correct?
A. That is correct. But all of that data is -- you know, there's lines everywhere and numbers and things and that's put into a logical sequence for the report. But you are correct, that original report is gone.
Q. And do you have a blank, if you will, pre-printed form that is -- that you still have access to that you use for the independent medical exams?
A. Yes. I don't have it with me, but that could be provided to you.
MR. LEWIS: We'll make a request for that blank pre-printed form.
BY MR. LEWIS:
Q. And what's the process -- how long did the examination take?
A. The entire interaction, the IME, usually takes 45 minutes or so. The actual physical exam

Page 18

will be probably roughly 15 minutes of that. And I don't recall in her case the breakdown of time.
Q. Did you do more than one exam that day?
A. I don't recall. Usually there are two or three that I do in a given day, but I don't recall.
Q. How many trips to Chicago's Rush Medical Center do you think you've made in the litigation -- in all litigation?
A. So since 2011, there's probably been five -- four or five. Again, that's an estimate.
Q. Okay. And you've probably done 75, roughly, exams?
A. Correct. But not all in Chicago.
Q. Where else have you done exams?
A. In Kansas City, Minneapolis. I think that's it.
Q. When you do an exam, how are you -- so when you do an independent medical exam -- or so-called independent medical exam in the context of litigation, how are you compensated?
A. Hourly.
Q. And do you have a rate sheet or some document that you would send to a lawyer? If I say, hey, Dr. Elliott, will you help me out and do an exam

Page 19

of my plaintiff, do you have a document that would send to a lawyer that kind of identifies your hourly rate and the cost and things like that?
A. Well, the only people that have access to me are through Ben Anderson's office and AWKO office, so I don't interact with any other lawyers. And the rate is a standard $700, regardless of what I'm doing, per hour.
Q. Let me ask you a little bit about your relationship with Ben Anderson. So Ben Anderson is an attorney in Cleveland, Ohio; is that correct?
A. Correct.
Q. And when did you first start working with Mr. Anderson in connection with litigation involving mesh products?
A. He contacted me in probably August of 2011.
Q. And what do you recall the nature of that conversation?
A. He had talked to me about being involved as far as the mesh litigation. I had made several talks around the nation against meshes, written an opinion paper against meshes and then have been contacted by Public Citizen -- Public Citizen -- the Ralph Nader Group in DC. He had read those

Page 20

and then he contacted me, so that was why he contacted me. And then it was about willingness to be involved as far as the litigation process.
Q. And do you have a retention agreement with Mr. Anderson? Is there some document that evidences your agreement to work for him or firms or plaintiffs?
A. In August of 2011, or perhaps September, but I imagine it was August, an agreement was signed -- a one-paragraph agreement that we were going to work together at a certain hourly rate, and if you don't get paid on time, we get penalized a percentage, and that was it. So there's no end date to it. Nothing has been signed since that time.
Q. And could you describe for me this concept of paying on time and penalized a percentage?
A. I informed him that I do not like working with lawyers because they tend to demand my work and then not pay on time. And he says, we will pay you on time. If not, it was -- and I don't recall the percentage. If it's over one month and you have not been paid, then you get -- there's a penalty to us, and it was like a 2 to 3 percent, which I've never had to invoke that.

Page 21

Q. Like interest or something?
A. Interest. Interest, yes.
Q. Okay.
A. Interest penalty. Let's put it that way.
Q. And that's what you've been operating under since 2011?
A. Correct.
Q. Has your rate changed over that time?
A. No.
Q. Now, the funds that you receive in connection with your litigation work, where does that go?
A. Where does it go?
Q. Does it go to you personally?
A. Yes.
Q. And do you have a company set up or is it literally just you as an individual?
A. Just me. No company.
Q. And is there any need to give those funds that you receive in connection with your work in litigation a portion or some of those funds to your current employer?
A. No, because that's -- it's all done on my own personal time. Hence the reason we're meeting over weekends and things. And all the IMEs, everything is done over weekends.

Q. Have you ever testified at trial?
A. Twice.
Q. How did you account for attending trials?
A. Vacation time or personal leave where I don't get paid.
Q. Do you have anyone that you work with on litigation that assists you with reports and research or anything along those lines?
A. No.
Q. And how do you -- how do you bill for your time? What's sort of the process?
A. Just a basic stopwatch, which is running right now. So whenever I do my research, documentation review, medical records review, literature review, I bill for that time. And so whatever client it happens to be for or general product -- and there's a -- it's itemized to that and sent to, again, Mr. Anderson at the end of the month.
Q. And that's your sole contact for purposes of sending bills is Mr. Anderson?
A. Correct.
Q. And the payments that come to you, do they come from all different law firms or just Mr. Anderson's office?

A. All different law firms.
Q. So Mr. Anderson is essentially the point person for the administrative aspects of your litigation consultation?
A. Correct. That's just what I was told to do, for ease sake, I suppose.
Q. Now, with respect to your work in the Clinton case specifically, I understand you haven't brought your billing records here, but do you have an estimate as to the amount of time you've spent on your work on Ms. Clinton's case?
A. On specifically Ms. Clinton, which the work was finished, you know, around the time of her IME, there was 17 hours spent reviewing the medical literature and the physical exam and write-up, which is obviously excluding the general report and the other IMEs on ObTape.
Q. So 17 hours on Ms. Clinton's case specifically?
A. Correct, as of September of 2015. That's not including with the work that's been done this month.
Q. And the work that's been done this month, excluding today, so let's -- obviously because we don't know how many hours you will spend today --

but excluding today, how many additional work have you done since September of 2015?
A. Well, it's roughly 45 hours. However, that's also including the general evaluation, so it's going to be very difficult to delineate specifically Clinton because the general is going to have overlap with her. But total this month, roughly 45 hours.
Q. And when we say "this month", we're talking July?
A. Correct. Up to yesterday. Not including today.
Q. Okay. So that's general plus Clinton.
Other than Ms. Clinton's 17 hours specific and the 45 hours this month for general work in Ms. Clinton's case, what additional amount of hours have you spent on the ObTape litigation, in connection with your consultation work?
A. Essentially, we're just looking at July, August and September of last year because nothing happened up until July of this year. Thirty-five hours roughly were spent on the general report back, again, that was last year. And then on the other roughly 10 mentor individuals, it was roughly -- and this is a guesstimate -- about 100

hours were spent on them.
Q. And that would be non-Clinton work?
A. Correct.
Q. And would Mr. Anderson have those records? I mean, all the bills that you sent for that work in ObTape, those would have all been sent to Mr. Anderson?
A. Correct.
Q. And with respect to your work in the Avaulta litigation, the hours in revenue could be determined by looking at records that Mr. Anderson has; is that correct?
A. That's correct. He would have all that.
Q. 197 estimate total.
And were the 197 -- I roughly did the math here, approximately 197 hours estimate, and I fully understand it's not an exact number, but that would be at the rate of $700 an hour --
A. Correct.
Q. -- all of that time?
A. Correct. And that's including travel time in there too.
Q. And then the expenses associated with that would be on top of the hourly?
A. Yes.

Page 26

Q. Do you bill for like out-of-pocket expenses, a hotel room, a lunch?
A. The majority of time I pay for those myself. I pay for the air travel and hotel myself.
Q. You don't bill that back?
A. No. The majority of the time. There are times I do. Usually I do not.
Q. So I have that as a -- I just did the math on my calculator. That's $137,900, again, estimating. Again, it's just an estimate. We have to look at the records.
Do you have an estimate for the amount of revenue that you've obtained overall from your work in litigation on mesh products?
A. No. I don't keep a total of that, no.
Q. And I assume that income is reported on your tax returns -- on your individual tax returns?
A. Correct.
Q. Do you do work in any other litigation other than mesh -- transvaginal mesh litigation?
A. Currently? In 2010, I believe, I worked with a patent infringement case. But otherwise, as far as the litigation process, it's only been mesh or transvaginal work, because remember Cook is not technically a synthetic mesh.

Page 27

Q. So mesh or transvaginal products?
A. Correct.
(Exhibit 4 was marked for identification.)
MR. LEWIS: I'm going to set that over here. That's just my notes for when I read the depo.
BY MR. LEWIS:
Q. When did you first start treating -- by the way, let's step back for a second.
You treat women for stress urinary incontinence as we sit here today? I mean, that is part of your practice?
A. Correct.
Q. And how long have you been doing that?
A. Well, technically since I started residency in '93. I did a fellowship in '99 which was treating females. It was a voiding dysfunction neurology fellowship. And then on staff since '99.
Q. And when you say "on staff", that's on staff of the Mayo Clinic?
A. Correct.
Q. And let me just back up for a minute. So the treatment of stress urinary incontinence, do you

Page 28

have an estimate of how many people are diagnosed with stress urinary incontinence in the United States? Whatever numbers you can come up with, either annually or total amount or percentage of the population?
A. There's numbers all over the place. It's difficult to ascertain exactly what they're talking about. If it's those treated or those diagnosed, those diagnosed is a very large number. I mean, it's probably well over a million. I don't know -- I can't tell you an exact number. And those treated, I've heard numbers between 300- to 500,000 a year, treated with anti-incontinence procedures. But the numbers vary. And, again, it just depends upon who's doing the reporting and if they're looking at Medicare, all-comers or what.
Q. Would you agree with the statement that female stress urinary incontinence is a significant health issue for women?
A. I agree and disagree. It is a major impact upon quality of life. It is not life or death.
Q. And when you say major impact -- so you would agree with the statement that female stress urinary incontinence has a major impact on the quality of life?

Page 29

A. It can in severe cases.
Q. In severe cases.
And in non-severe cases, can it also have a major impact on the quality of life?
A. Typically not.
Q. Do you believe that the treatment of stress urinary incontinence is important for female -- female health?
A. Well, if you're talking about the survival -- long-term survival and shortening of life, no.
Q. In terms of quality of life, is the treatment of stress urinary incontinence an important function?
A. It can be, yes.
Q. When you talk about quality of life for women who have stress urinary incontinence, could you describe for me the quality-of-life impact that can occur with women who have stress urinary incontinence?
A. There can be issues of embarrassment, worries about odor, unwillingness to do physical activities, go out shopping, walking, aspects along that lines.
Q. Can stress urinary incontinence cause women to choose to be less active than they would

Page 30

otherwise be if they did not have stress urinary incontinence?
A. It can be.
Q. Can a woman's reduction in activity levels lead to other co-morbidities associated with their health than if they had been more active?
A. Theoretically that's possible, yes.
Q. Have you seen that in your patient population?
A. No.
Q. Are you aware of that occurring in other patient populations involving women with stress urinary incontinence?
A. Well, we're talking a large generality here. Some women will reduce their activity levels. Does that correspond to shortening of their life? I've never seen any data, no studies done on that, so again, we're talking about a hypothetical.
Q. Sure.
So 1993 is roughly when you started treating women with stress urinary incontinence?
A. Actually, that's when I started residency. It actually had been '94 when I actually started urology. The first year was general surgery, which you have minimal exposure to female urology,

Page 31

so '94 would have been more accurate, as a resident.
Q. And what products, if any -- surgical intervention products were you using in 1994 to treat female stress urinary incontinence?
A. Pubovaginal sling -- autologous pubovaginal sling.
Q. PVS stands for pubovaginal sling; is that fair?
A. Correct, yes. But this was autologous pubovaginal sling.
Q. Could you describe what autologous means?
A. Autologous is using the patient's own tissue, so harvesting a piece of fascia from the patient. So it is not synthetic and it is not someone else's. It is their own. So that's where the "auto", meaning self.
Q. And is there a particular location where you harvest the autologous sling material when you do a surgery or does it depend on the patient?
A. The majority -- well, from my practice, it's always going to be the rectus abdominus fascia. Other individuals will use fascia, a lot of it, but I don't do that, but that has been done and reported.

Page 32

Q. And are there risks associated with the use of pubovaginal slings -- autologous pubovaginal slings?
A. There are risks with all surgeries.
Q. Okay. So would PVS autologous -- by the way, do you quote an efficacy rate for PVS when you talk to a patient?
A. When I'm doing that type of a -- yeah. The short answer, yes.
Q. And what is that usually quoted?
A. 80, 85 percent dry; 10 to 15 percent improved; and whatever the remaining is, 5 percent or so minimal improvement or less-than-ideal improvement.
Q. 10 to 15 percent improved?
A. Correct.
Q. And the risks? What are the main risks of PVS surgery autologous?
A. Failure of the procedure.
Q. And would that be a need for further surgery?
A. For -- possibly. It depends on the severity and the patient's desires.
Other risks include bleeding at the harvest site; trocar injury to the bladder; rare but it's been reported, injury to the intestines

Page 33

with patches of trocars, so it's usually an avoidable step. Urinary retention has been reported. Urinary frequency/urgency afterward has been reported. That's the -- that's the main complications.
Q. Infection?
A. Wound-site infection, superficial infection. Usually it would be treated with antibiotics.
Q. Erosion or otherwise rejection of the material?
A. It doesn't happen because it's self, so you don't have erosions -- I've never once seen an erosion or heard of it with the pubovaginal autologous sling because it's self so there's not the rejection issue of the foreign body issue with it.
And the infection I'm talking about is on the abdomen with the harvest site. I don't know if I mentioned that or not.
Q. That sounds like a pretty good -- a pretty good surgery to treat stress incontinence, yeah?
A. I don't know what you mean by "good surgery".
Q. Well, I mean, it's 80 to 85 percent cure -- dry, right?
A. Correct.

Page 34

Q. No risk of deep infections, maybe a wound-site infection, some harvest issues at the site, but for the most part, seems like a pretty successful surgery, right?
MR. KREIS: Object to form.
THE WITNESS: The procedure has been around a long time, has a long track record. There's a lot of data on it. When performed by people who know what they're doing, it's a safe and reliable surgery.
BY MR. LEWIS:
Q. And you would say that today, right, that PVS is safe and reliable?
A. Yes.
Q. How many surgeries do you think you've done over the course of your career involving pubovaginal slings autologous?
A. Just autologous?
Q. Yeah.
A. Numbers are going to vary tremendously over the years. For the first few years I was on staff, I was doing 100, 150 a year. Then when mesh slings came out specifically in the urology area of the -- the TOT slings, the transobturator slings, I continued that number of 100, 150, and

Page 35

then it progressively became less and less as more general urologists and gynecologists were doing it. Then my practice swung over to be fixing complications of slings.
So my numbers of first-time autologous slings are lower. Now I'm doing the reconstruction after failed usually mesh slings elsewhere. So now I'm probably doing about 30 of those a year. For a while there -- for years it was down to zero because the mesh slings were so -- so popular.
Q. And this was in your practice?
A. Well, my practice and major academic centers. For example, Dr. Webster at Duke who does also a practice very similar to mine who is a reconstructive urologist like myself, the same thing happened when private practice urologists and GYNs started doing more and more of these. Because the pubovaginal sling is a bigger surgery, most urologists shied away from it. Same with GYNs. Mesh slings came out and became available to everybody.
Q. So I want to talk just about your practice. So you used pubovaginal slings autologous in your practice since roughly 1994. And have you used

Page 36

that same surgery -- or that same product for your entire career?
A. Well, yeah. That's an autologous sling but the numbers have varied tremendously over the years.
Q. Understood. But I mean, you have never said, I'm not doing that anymore?
A. That is correct. That is correct. Never stopped.
Q. Never stopped, as in --
A. Never chose -- I'm sorry to interrupt. I never chose to say I'm not going to do this because it's a bad procedure.
Q. And over the course of time from, you know, '94 to present, you have used PVS autologous in kind of what percentage? What's the variance in your practice? I know it's gone up and down. Would you say anywhere from zero percent of my practice at one point in time to 100 percent of my practice? If that's the answer, that's the answer, but I was kind of looking for a range.
A. From '94 to '99 it was 100 percent. I was a resident at that time. The staff I worked with who did this chose only to use this product for fear of the meshes and for fear of ProteGen.

Page 37

From '99 to 2000, it was 100 percent cadaveric pubovaginal sling, which we used Tutoplast, T-U-T-O-P-L-A-S-T, from Mentor Corporation.
Q. Okay. Let me stop you right there. So from '99 to what period of time? I'm sorry.
A. To 2000. So it was the summer of '99 to the summer of 2000, it was 100 percent cadaveric.
Q. So that would have been cadaveric. Would you call that CVS? No. How would you --
A. Well, you would just call it cadaveric pubovaginal sling, but you would call it, for this sake, CPVS, but...
Q. So cadaveric pubovaginal sling.
And you used Tutoplast?
A. Tutoplast only. Well, we tried some others and had problems, which we wrote up a paper on, but primarily Tutoplast because we found that it worked.
Q. And that was Mentor's product?
A. Correct, at the time, which then became Coloplast.
Q. And that was 100 percent of your practice?
A. Pretty much except for some mild variances using dermal slings or something like that. But

Page 38

it was primarily -- let's say 99 percent cadaveric that year.
Q. Okay. Why the switch from autologous to cadaveric in '99?
A. I started doing my fellowship at a different institution and that staff liked using cadaverics. They did not want to use meshes but wanted to use cadaverics.
Q. What institution were you at prior to '99?
A. Well, I did my residency at the Mayo Clinic from '93 to '99. From '99 to 2000, I was at Baylor College of Medicine in Houston doing the fellowship work in advanced reconstructive voiding dysfunction neurodynamics.
Q. So that was '99 to 2000 Tutoplast. Okay.
Take me now to 2000.
A. So when I came back and joined the staff -- re-joined; I was hired already -- then it was probably 75 percent cadaveric, 25 percent autologous, and that continued until roughly 2003 -- 2002, 2003.
Q. So it was -- I'm sorry. It was how much autologous?
A. Roughly 25 percent.
Q. Okay. And 75 percent, roughly, cadaveric?

Page 39

A. Correct.
Q. Now, at this point in time, in 2000 when you came back to Mayo Clinic, you now were outside of a residency and fellowship and were now in your own practice; is that correct?
A. That is correct.
Q. And you were now seeing patients who were coming to you, Dr. Elliott, help me with my stress urinary incontinence, right?
A. That's correct. I was not under the umbrella of somebody else as a student, so to speak.
Q. And you had the option to choose the treatment for the patient, obviously in connection with informed consent and things along those lines, but you had the option to recommend how to treat stress urinary incontinence for the patients that came to see you, correct?
A. That is correct.
Q. And between 2000 and 2003, you varied your recommendations to patients. Some patients you recommended autologous pubovaginal slings. Other patients you recommended cadaveric pubovaginal slings; is that right?
A. Correct. And I should probably say it was like 2002, because right around that time, 2002 to

Page 40

2003, somewhere -- I don't remember exactly when, is when AMS came out with their suprapubic sling. And then so then we -- I swapped over to nearly 100 percent to that. So I just wanted to make sure we have a timeline.
Q. Sure. I have it 2002, 2003, I think.
But I kind of want to go back to this recommendation. So at the time, 2000 to 2002-ish, 2003-ish, you were making recommendations that could either be autologous PVS or cadaveric PVS; is that right?
A. Correct.
Q. When a patient came to see you during that time frame and they wanted to have their stress urinary incontinence cured, what did you do to educate yourself about whether PVS slings were safe for patients?
A. Well, by that time the pubovaginal sling was originally described in 1984 or so, '84, by Dr. Ed McGuire at the University of Michigan. So there was at that point, what, 15 or so years of papers out there on the products -- on the procedure, the complications, the long-term benefits, the long-term risks of the autologous.
The cadaveric there was much less.

Page 41

I wrote up one of the cadaveric papers in '99, or I think it came out in 2000 or so. So there was less information on the cadaverics. But autologous had, again, a 15-year track record or more.
Q. Was that important to you?
A. Yes, it was.
Q. Why?
A. A surgeon should know everything possible about a product and the surgery and the risks and benefits to be able to inform the patient adequately -- or "completely" is a better word to use.
Q. Let me make sure I get this right. You would agree that a surgeon should know everything about a product or procedure before recommending it to a patient?
A. My opinion is that the surgeon has a moral, ethical obligation to know completely how to perform a surgery, to treat essentially all the complications of said surgery, and to inform the patient of the risks and frequencies of that surgery that's been reported in the literature or otherwise and also what their own personal experience is. So it goes beyond just quoting

what somebody at Hopkins does. What -- in my own hands, what the surgery risks are. Because the patient is not undergoing a surgery at Hopkins. They're undergoing a surgery with me.
Q. So you would agree that a surgeon has a moral and ethical obligation to know how to conduct a surgical procedure before recommending it to a patient, correct?
A. Yeah. Not just conduct but to do it well. So it's not just competence. Surgical competence is the lowest rung. You have to be, in my opinion, an expert before you do surgeries. Otherwise you're going to harm patients, potentially.
Q. Let me just -- because I want to make sure I get this right. So this is surgeon's obligations. So a surgeon has a moral and ethical obligation to know how to conduct a surgery well before recommending it? I want to make sure I get your words right.
A. Be fully competent in performing the surgical technique.
Q. Okay. To be fully competent in performing the recommended surgical technique?
A. Well, whatever surgery they're going to be

doing, correct.
Q. So would you agree with "recommended surgical technique"? In other words, if I'm a surgeon and I'm going to recommend a particular surgery for a physician, you believe that -- or for a patient, you believe a surgeon has a moral and ethical obligation to be fully competent in that surgical procedure?
A. Well, just not to be difficult, but for clarification, if I say I recommend this, it doesn't mean that I'm going to be doing it.
Q. Okay.
A. If it's going to another doctor, they have to be. So I'm saying personally, doctor/patient relationship and I am going to be doing the procedure, then the procedure that is recommended to be performed by that doctor, just so we're clear.
Q. Right. That's actually a very good point, so I appreciate the clarification there.
So a surgeon has a moral and ethical obligation to be fully competent in the surgery that that surgeon is going to perform?
A. Correct.
Q. Now, let me ask you the -- you may think this

is a silly question but I'm going to ask it anyway.
Why? Why do you believe that a surgeon has a moral and ethical obligation to be fully competent in surgery that the surgeon is going to perform?
A. I mean, that goes back to the basics of care. First, do no harm. And in my practice as a reconstructive surgeon, I am picking up the pieces of less-than-ideal surgical technique elsewhere, and had they been performed by an expert, you can avoid certain complications. There are preventible complications and then there are, for lack of a better phrase, Act of God complications, like a heart attack. You know, you do everything right and a bad outcome.
But the surgeon who is going to be picking up a knife has a responsibility -- or a treating physician, family practice or otherwise who's going to be prescribing medication -- you need to be informed. We are going to be the point person for that patient, and we have -- so you have to prevent complications.
Q. And you've seen this in your practice in treating patients with complications associated

with slings and other products, I assume, that there have been less-than-ideal surgical technique issues that have caused a complication?
A. That is correct. That can happen.
Q. And because surgeons and their technique can contribute to patient outcomes and potentially cause complications, that's one of the reasons you believe that a surgeon has an obligation to be fully competent in the surgery that they're going to perform?
A. A long way of saying it, but yes. The surgeon better be careful when he picks up a knife because you have a human being you have to protect. They're trusting you.
Q. And let me ask you this: So when you were using -- when you were using the PVS autologous and PVS cadaveric in your practice between 2000, 2002 and 2003, were you in your mind fully competent in both of those surgeries?
A. The surgeries are -- yes, because I was starting to be trained by a trained female urologist large volume. So I was -- those first six years from let's say '94 to the summer of 2000, I was under the guidance of a fully competent, high-volume surgeon. So I was trained

Page 46

by arguably some of the best. That's -- there's no way to prove the best surgeon, but by very high-quality surgeons. Then I went out to do it on my own. So it's not like I just began to do it willy-nilly. And that's also in conjunction of doing fellowship work, which is doing more advanced anatomical studies and things. So yes, I felt fully competent.
Q. Now, would you also agree that a surgeon has a moral and ethical obligation to understand the risks and complications associated with a product that they are going to use in a surgery with a patient?
A. The surgeon needs to know and need to be told all of the risks of a product, whether it be a heart implant -- heart valve implant, stents, you name it. They need to be -- and if the surgeon is told all of the risks that are known, then the burden is on that surgeon to then relay that on to the patient.
Q. So the -- and I just kind of want to understand this -- this nature of knowing of the risks and complications associated with a product to be used in a surgery. Do you believe that a surgeon has an obligation to do independent -- and

Page 47

I say independent from the manufacturer of the product -- independent study analysis, diligence, before using a product in a surgical procedure?
A. It depends upon the product and how well that product is known. Certain new products in the market, there will be no other independent research out there. Then you are wholly reliant upon the company to tell you those risks. If it's let's say the pubovaginal sling -- well, of course, that's not a -- we'll say the cadaveric sling, okay? Specifically the Tutoplast sling, which had been around a long time. There's a lot of data. In my personal opinion, it's not a new procedure. The surgeon's reliance upon the company is going to be less in that situation and more reliant upon the data that's available. But, again, it's going to be product-to-product dependent.
Q. So let me talk about -- let me talk about what I think you said, that a surgeon has to be fully informed of the risks -- a surgeon has an obligation to be fully informed of the risks associated with a product prior to using it in a surgical procedure. I mean, you would agree with that?

Page 48

A. Yes. That surgeon, prior to implanting a product, especially if it's a new product, needs to be fully informed of all known risks with that product.
Q. A surgeon needs to be informed of all known risks associated with product. And I say before using in a surgery? Does that sound right?
A. Correct, correct. If he's using it independently. Now, sometimes they'll be using it under the guidance of a more competent or fully trained surgeon and then the ball game changes. But I'm just saying if you're independently doing it, it is your responsibility, and then to relay that on to the patient.
Q. For using in a surgery.
Okay. I just want to make sure I have this right. So you would agree that a surgeon needs to be informed of all known risks associated with a product before using in a surgery?
A. Correct.
Q. And there's a sliding scale -- you would agree there's a sliding scale that with newer products, much of that information is going to come from the manufacturer, and maybe with more

Page 49

established products, a lot of that information can come with the experience of other surgeons who have used the product or of the published data? There's sort of a sliding scale there, you would agree?
A. Correct. For example, let's just say urethral catheters that have been out for 50 years, we're not relying on the product insert. A brand-new product, we're relying on it heavily.
Q. Okay. In 2000, when you started using cadaveric PVS Tutoplast in your practice -- and that was 75 percent of your practice between 2000 and 2002 -- what did you do to educate yourself about the safety and efficacy of that product?
A. The staff that I learned from in Houston had been using it for years, so I had his expertise. But then I wrote up a paper on it, which is out there which is in my CV, on are all fascia latas -- actually, I don't even remember what the title of the paper is, but it came out around 2000 or so. So I did a thorough literature search of all available literature out there, which is referenced in the paper, about the product, the known risks and various different complications.
Q. So you -- you believe that it was important

that you did a literature search related to the product, cadaveric PVS, prior to using it in your surgery?
A. Not necessarily that. I was writing up a manuscript. So it is essential if you're going to write a paper, you have to do a literature search, so that further augmented my learning. I wasn't just taking what my staff said verbatim. However, he had many years of using it. I don't know how many years. So then you talk to them about his various different complications, how he managed them or avoided them.
Q. So you used your -- you used the experience of others that you felt were credible physicians in informing of you of whether or not a Tutoplast was safe; is that right -- the folks in Houston?
A. Yeah, I would say that's correct. This is somebody I knew and worked with for a year and he was using it on his patients and he felt in his hands it was safe and then he taught me how to do it. So it wasn't -- I wasn't trusting the opinion of someone in a different state. It was somebody I was working with.
Q. Sure. Understood. And I didn't mean to suggest otherwise.

One of the things that you did to satisfy yourself that Tutoplast and cadaveric PVS was a safe product for your patients was to consider the experience of other physicians who you respected?
A. Correct.
Q. And then another thing that you happened to do -- and maybe this isn't required in every instance, but you just happened to do in connection with your research -- was to do a literature search related to that product. Is that fair to say?
A. Well, I did. I mean, that was because I was writing up a paper but very, very few people write up papers so that was unique to me.
Q. It was unique to you, but that was one of the things that informed your conclusion that Tutoplast is a safe product for your patients?
A. That is correct. That Tutoplast specifically was and how it was manufactured. It was aerated and not freeze-dried. So in our paper conclusion, that freeze-dried cadaveric tissue broke apart. So in our research, everything we found out that other products out there were not good.
Q. And then the other thing that you considered

in connection with determining that Tutoplast was a safe product for your patients when you started using it in 2000 with your own individual patients, was information provided to you by Mentor?
A. Correct. They had a -- they had a product insert with it and that's where I learned as far as its processing.
Q. And do you still use Tutoplast today?
A. Yes, but it's changed named names. It's not called Tutoplast. And I still ask for Tutoplast and they give it to me. But it's called Coloplast, which was bought out by Mentor -- the other way around. Excuse me.
Q. And in dealing with Mentor with respect to Tutoplast, did you work with the specific individuals at Mentor in the urology group? I mean, were there people that you talked to -- specific names and individuals that you talked to?
A. Yes. I talked to Terri Oto, spelled -- it's O-T-O. And then main contact person was Chris Sellwood. I also talked with, more socially, Dave Amerson. And I'm not sure if I talked with Ray Tantillo. I can't recall on that. I know the name but I don't know so I can't -- I won't go

there.
And then I also forgot to mention that Mentor did fly me out to New Jersey to work -- to observe surgery with David Chaikin, who's in Short Hills, Jersey -- New Jersey to watch him do the product and also for prolapse. And then also to California with Dr. -- he's at Cedars-Sinai and I'm blanking on his -- oh, Gary Leach, L-E-A-C-H.
So above and beyond my training at Mayo and at Baylor, then I saw those two high-volume surgeons perform surgeries, and Mentor paid my way up for that. I forgot to mention that earlier.
Q. And that was for Tutoplast?
A. Correct. Tutoplast, using it either as a sling or also as a prolapse repair, which I still use today.
Q. And do you maintain contact with either Chris Sellwood or Dave Amerson today?
A. Zero. Chris Sellwood left the company -- actually, I don't recall exactly when he left the company. 2005 or '6 or thereabouts. I don't know on that.
And Dave Amerson, last contact I had

with him was maybe 2009. That's a guess. And, again, I don't think he's with the company either.
Q. And Terri Oto, I assume you haven't talked to her in many, many years?
A. None. She was all of a sudden gone from Mentor and I asked why, and they said it's an internal issue and she's gone. And that was -- I don't recall the date, 2004 or 2005. Chris Sellwood left after that. I do know that. And then also then after that was then Matt Prischmann, who was the regional rep after Sellwood left.
Q. With respect to Tutoplast, do you believe that that product is a safe and reliable product for the treatment of stress urinary incontinence?
A. I think it is a good product. It is safe. It's reliable. There's a long track record.
I think the data has panned out that autologous slings are better and that's why now currently I've gone a shift that cadaveric slings are actually the minority of the slings that I do. So there's an evolution there that's gone on for me.
Q. Okay. But I mean, in your experience, would you characterize Tutoplast as good, safe and

reliable?
A. Yes. It is good, it is safe, it is slightly -- if you believe the data, which I do, slightly less efficacious than autologous pubovaginal sling but is not a bad product, by any means. I still use it.
Q. And did you feel that, in your dealings with the individuals at Mentor related to Tutoplast, that they were open, honest and trustworthy in disclosing the risks and benefits of Tutoplast to you?
A. I thought with my interaction with them, that I was being told everything. That's what I believed.
Q. And sitting here today, do you still hold that belief?
A. With Tutoplast, I think that has been a fair assessment, especially with Terri Oto, yes.
Q. And when you say "especially with Terri Oto", what do you mean?
A. In my experience -- just mine, no one else's -- I found that she was seemingly very forthright in her opinions, whether it would be good or bad, and tried to push forward scientific learning. They helped fund a study that I was

doing with no guarantee it would be beneficial for their product at all, and so I appreciate that.
Q. And so do you find that your dealings with Mr. Sellwood and Mr. Amerson with respect to Tutoplast were equally -- found them to be forthright and trustworthy?
A. Well, Mr. Amerson I don't recall specifically talking about Tutoplast, so let's exclude him from the equation.
Mr. Sellwood, I don't -- looking back on it, I don't believe I was ever told anything that didn't pan out to being true, specifically with Tutoplast.
MR. LEWIS: We've been going about an hour. Quick break? Five minutes?
MR. KREIS: Sounds good.
(Recess taken from 9:57 a.m. until 10:07 a.m.)
BY MR. LEWIS:
Q. Now, Doctor, we were talking about surgeon obligations prior to using a product, and I was sort of talking about those issues in the context of your use of cadaveric pubovaginal slings and autologous PVS and so I kind of wanted to get back onto that topic.

And I believe that another obligation that you had indicated in an earlier answer, and so I just took some notes on it, was that a surgeon needs to inform the patient of the risks and benefits of the surgery, both from the -- their own experience and from general knowledge; is that correct? Did I get that correct? You said something about your own experience. You mentioned Hopkins, and I just wanted to clarify what you meant by that particular --
A. I think it's important for a surgeon, when he's discussing the various procedure with a patient, to inform the patient of what is known out there, not necessarily that surgeon's own experience, but then also include in the doctor's own experience for results and complications.
Q. So would you agree that a surgeon needs to inform a patient of known experience and personal experience related to a product before a surgery?
A. All known, yes.
Q. Okay. To inform patient of -- should I use "risks" or "experience"? What should I --
A. Well, "experience", which includes the risks and the success of the procedure. "Experience"

Page 58

would be an all-inclusive term. Risks and results would be more specific.
Q. So known experience, including risks associated with a product before using on that patient? Is that fair to say?
A. Yes.
Q. So a surgeon needs to inform a patient of known experience, including risks, associated with a product before using on that patient. You would agree with that?
A. Yes.
Q. Okay. And the surgeon needs to inform a patient of his or her own experience, including complications associated with a product before using it on that patient?
A. Correct.
Q. Okay. I'll just use his or her because we do have both genders in this litigation.
And so what did you tell patients with respect to those two topics, known experience and your experience, when you started using Tutoplast in, you know, 2000 through 2002?
A. I don't recall what the -- it was a long time ago. I don't recall what the conversations were, other than there's a long track record with

Page 59

them -- these specific ones, and usually discuss what my numbers are.
Q. And what were those? Did they vary over time or did you --
A. My numbers?
Q. Yeah.
A. Well, yeah, my numbers are always going to increase. They're never going to reduce.
Q. Sure.
A. Again, I don't know how many I had done at that point in time. There are probably several hundred.
Q. And then as far as -- I guess by numbers I meant like success -- percentage success, percentage complication, that sort of thing --
A. Yeah.
Q. -- with cadaveric.
A. I would have been quoting the numbers that we did in our study from Houston because those are procedures that I did under the guidance of the staff.
Q. So with PVS cadaveric, study numbers that were published?
A. Correct. Well, they were in the process of being published. I don't remember when the paper

Page 60

came out, but the paper had already been written and submitted.
Q. Okay. And that would include efficacy and risks?
A. Correct.
Q. And that's what you pretty much stuck to whenever you talked to a patient about cadaveric PVS?
A. Correct.
Q. Do you remember what additional complications a cadaveric PVS has that an autologous PVS does not?
A. You're not harvesting any tissue, so you reduce those various different risks of wound infection. The other dissection in the vagina and the risks -- or as far as failures are mainly what we were focusing on. But the biggest benefit is you don't have to harvest tissue, so there's less pain, less recovery, faster out of the hospital, faster back-to-work time.
Q. It's really a separate step that doesn't need to be undertaken during the surgery itself and then another place where the patient doesn't have to heal, essentially?
A. Correct.

Page 61

Q. And then added risk is things associated with a foreign body?
A. Yes and no. It is foreign, meaning it's not the patient's self, but it's not a synthetic. So the foreign body risk is essentially nonexistent. The basic risk with these cadaverics is failure, efficacy.
Q. Is there a risk of erosion with cadaveric PVS?
A. I've never seen it because it's not a foreign body within there, so you don't see that reaction, the immune response to it.
Q. Is there a risk of infection?
A. On the abdominal incision, yes. I've never once seen it in the vagina side of it.
Q. Have you heard about it in the literature?
A. I've never heard of it in the literature, no. But, again, on the abdominal incision side, yes, a superficial infection, cellulitis, can occur.
Q. And what would you say the efficacy rates -- do you have them kind of in your mind or do you really need to look at your study to --
A. Well, they're going to be -- I think with my literature and then with the literature of others, it's been showing that it's slightly less as far

Page 62

as the dry and improved and slightly more and the minimal improvement. There's going to be a slight lesser efficacy. It's not a huge amount. But, again, there's papers all over the place as far as that goes, so it's -- the general consensus, it's going to be slightly less efficacious. It doesn't mean I don't do it anymore. It just means it's slightly less efficacious.
Q. So back in 2000 to 2002 -- let's assume it's slightly less efficacious -- we're still talking close to 80 percent success rate, I would assume?
A. Correct.
Q. And probably, you know, add another 10-ish percent on top of that for improvement?
A. Correct.
Q. How did you describe for a patient, okay, you can -- we can go with this route or we can go with this route, autologous versus cadaveric? How did you describe that for a patient or did you make that decision yourself? Did you pick one for the patient and go one path?
A. There's not going to be one single right answer to that question. Certain times, if we have a patient who's morbidly obese, we're going to say, here are the two options but you should go

Page 63

down the route of cadaveric because it's going to be a very difficult surgery because you have abdominal wall fat of ten inches.
Other patients who have had multiple abdominal surgeries, we're going to say, here are the two options but we should go down the cadaveric because your tissues probably aren't going to be very good. If they've had radiation, it would be the same answer. We can do both or either/or but it would be better if we go cadaveric.
On an individual who was relatively thin in otherwise good health who would have good tissue if we harvested their own, then we say, here's your choice; here are the pros and cons; and then let the patient decide.
Usually they were more likely to go down the cadaveric route, because it was easier, faster, less pain. Others would say they didn't want that. So, again, it was a discussion. Sometimes it's more of a guided discussion based upon the patient's risk factors. Other times it was a completely open decision on their part.
Q. Well, let's get to 2002, 2003 time frame. Was there a change in your practice in what

Page 64

products you used for surgical treatment of female stress urinary incontinence?
A. There was a dramatic change when the SPARC product, S-P-A-R-C, by AMS came out, which is a suprapubic sling. TVT came out when I was a resident in, what, '95, '96, around that time frame. There was in the individuals I worked with a tremendous amount of fear. There were reports of death, unknown. And surgeons, urologists typically did not feel comfortable doing from the vagina up. So when SPARC came out, this was mimicking what we did with the autologous pubovaginal sling or the cadaveric. I mean, the trocars go from the top down.
So I was one of the first in the state -- this state, Minnesota -- to do one. And we used specifically the AMS product. And then with that it became an outpatient procedure, which was almost unheard of in urology, and there was a dramatic shift to doing the SPARC, so such that it became almost 100 percent of what I did.
Q. Okay. And let me back up. I forgot to ask a question that was spurred by some earlier testimony.
When we were talking about -- and I

Page 65

think I have this correct so let me see if I have this correct. A surgeon -- when we were talking about a surgeon's obligations, a surgeon needs to inform a patient of his or her experience including complications associated with a product before using on that patient. You agree with that?
A. Correct.
Q. Okay. Why is it that that's important, the surgeon's own experience versus somebody at Hopkins or somewhere else?
A. The patient, from my opinion, needs to know what is a realistic expectation when I am the surgeon. They want -- and so if I quoted Hopkins data, that's not me doing the operation. So I feel that it's the surgeon's responsibility to say, in my hands, this is the risk X, Y and Z. This is the odds of success. This is the odds of minimal success. This is the odds of failure. Because I watch my data. Now, unfortunately most surgeons don't have accesses to the resources I do to be able to do that. It makes it much more difficult. But that's my personal feel, that you have to quote that.
Q. And is there -- can there be differences in

Page 66

the performance of a product in the hands of different surgeons?
A. It depends upon the product. Some procedures are highly complicated. Let's say like a hip transplant, okay? That's very difficult to learn and a lot of learning involved with it. Other ones are simple. Catheters, you know, there's not much difference. So it's going to depend upon the product.
And there's the data out there that high-volume surgeons at high-volume centers will have good results, and that's in thyroid surgery, prostate surgery, ortho surgery. It's across the board. I've never seen it with incontinence surgeries but other surgeries, yes.
Q. But let's talk specifically about surgical treatment for female stress urinary incontinence. Is it your opinion that there can be varying degrees of success with respect to surgical treatment of female stress urinary incontinence from surgeon to surgeon to surgeon?
A. The only study that I know of that addresses that would be Jennifer Anger's data out of Cedars-Sinai, that looked at what has been reported in complication various databases in the

Page 67

Medicare population. And the lower-volume surgeon -- and it was specific on efficacy and re-admittance to the hospital, lower-volume surgeons had a higher risk than high-volume surgeons and hence, it was that paper's recommendations that a surgeon needs to quote their results, not necessarily the expert's results.
Q. And that has informed your informed consent process as well, in addition to your just overall opinions? But that paper is something that's, I guess, meaningful to you?
A. Correct.
Q. It's a reliable authority, I guess, would be my specific question, in your mind anyway?
A. Possibly. That study has not been reproduced by anyone else. So any study that comes out, you have to take with a grain of salt. It needs to be reproduced by others. I have no reason to doubt it. But once it's proven -- there's always going to be initial studies that say one thing and then you need the multiple studies to then back it up or disprove it.
Q. All right. So beginning in 2002, you start -- and correct me if my dates wrong but I

Page 68

was thinking this is what you said. Beginning in the 2002-ish time frame, you start using the top-down retropubic approach with the SPARC sling?
A. Correct. By AMS, yes. And it was in that time frame, and I don't remember exactly when, and it was a dramatic change in my practice.
Q. So describe for me the process that you went through in deliberating whether to introduce the SPARC sling in that surgical technique -- that surgical procedure as an option for your patients? What did you do to make sure that this was a safe thing for your patients?
A. During that time frame, there was a large push within urology to come up with an outpatient sling. It was already in existence in GYN. GYNs almost exclusively used TVT. The TVT was used minimally within urology. So there was a desire for an outpatient sling. AMS was the first one that I know of that came out with one.
AMS is based here in Minnetonka, close by here, so they have easy access to where I work. And they presented their idea. I watched the surgical videos on it. And it is essentially -- it's a fairly simple procedure. And, again, it mimics what we already did with the

Page 69

autologous sling or the cadaveric sling, except you don't have to harvest any issues. So it was a tremendously easier procedure to do.
And then I read whatever -- there was no data out on it. I read the -- what the company said, the IFUs, as they called them, instructions for use, and watched surgical videos and then did it. And then I also then -- at some point in time I observed or came up here for cadaveric labs with it, and I don't recall the time frame with that.
Q. So prior to 2002 -- now, at this point in time in 2002, just to kind of clarify because you've drawn this distinction between gynecology and urology. You're a urologist?
A. Yeah. A urologist trained in female urology, female pelvic mesh and reconstructive surgery.
Q. Okay. It was your understanding that gynecologists have been using outpatient surgical procedures to treat female stress urinary incontinence prior to 2002?
A. Correct. I mean the TVT came out in '96, '97, thereabouts. Ulmsten was a gynecologist. It came out -- and Ethicon was much more involved in GYN than urology, and so it took off and went like

Page 70

crazy and very poorly accepted within urology communities.

Now, that has somewhat changed now, but that's a fair estimate. And again, a rough estimate that I heard back then it was like 90 percent of the TVTs done were done by gynecologists, not urologists, so --

Q. Do you have a view -- sorry. I didn't mean to interrupt you.

A. No. I was done.

Q. Do you have a view as to why it was more accepted in gynecology than urology -- the TVT procedure?

A. Well, it was initially introduced to GYN. And so by the time it takes for papers to come out, publications, it's going to take two or three years. And then there were the reports of the complications, deaths, things from the trocar. Urologists were very -- very comfortable, like myself, of passing the trocars from top down. Didn't like the idea of passing it from the bottom up. Didn't feel like we had as much control. That may be surgically accurate or bias but it's what it was. So that's why it just took time, rather than once the SPARC came out, then it was a

Page 71

huge adoption within urology, and then the TVT was not needed in urology.

Q. So beginning in 2002 in your practice -- and now you've been -- you've been at this on your own for a couple years by now -- were you having good results with the cadaveric and autologous pubovaginal slings?

A. Yes.

Q. Okay. Why would you look to move away from that success and try something that had no data?

A. Patients were wanting outpatient minimally invasive procedures. The pubovaginal sling -- the autologous requires a day or two in the hospital. The cadaveric is a little bit less but still it's an overnight stay in the hospital. So there was a desire to be able to provide a same efficacious, fewer complications and outpatient procedure.

Q. Yeah. But I mean, this wasn't even -- you said yourself that there was really no data on this at the time that you started using it. I mean, wouldn't you want -- how did you satisfy yourself that the use of this synthetic material in a surgical procedure was safe for your patients?

A. The TVT and the AMS mesh, if you hold them up

Page 72

side by side, look identical. There's still the outer wrapping and everything. And so what we were told from AMS is, hey, it's working in the TVT group, which we had papers out there they were efficacious. Ulmsten's papers showing it was efficacious. So saying why not try it. There were -- all these reports of mesh complications had not been out yet. We had not heard of them. It was still early on. So there was nothing presented to us from AMS to say it's bad. It was all good. And a lot of that relied upon the TVT data that was out there. In hindsight, I wish I would have not gone down that route but I did.

Q. Tell me about that. You wish you hadn't started using SPARC?

A. Correct. All meshes, except for highly select cases, which are pretty rare now.

Q. So I want to speak specifically to the SPARC sling and its use in your practice.

How many patients have you implanted with a SPARC sling?

A. It's a good question. I don't know exactly because when the Mentor product -- the ObTape came out, I stopped using it completely and then started using it again but still had the same

Page 73

problems with it because we had problems with -- the adapter was large and was tearing the bladder. So a certain percentage of patients, roughly 5 to 10 percent, were having torn bladders. So that's the whole reason why when ObTape came out I wanted to swap away from it. So then I used it for a while until Coloplast came out with their Aris.

So I can't tell you a number. It was probably a couple hundred of the SPARCs, but that's really a rough estimate because it's stop, start and...

Q. You've never undertaken to go back and look at your records to see how many you've implanted?

A. No.

Q. Have you undertaken to go back and see how many experienced complications with SPARC?

A. No. The complications I was referring to were intra-op complications. I was unaware at the time of long-term issues, so we didn't create a patient registry like I have now.

Q. You have a patient registry now?

A. Well, for the slings that we do -- patient -- it's a glorified name for just a database where we keep everybody's name and the procedure we do, correct. But that's all -- there is no -- I have

Page 74

not done a mesh sling in -- since the middle of 2013, roughly. Roughly three years.
Q. But you still have the records from your SPARC patients, I assume?
A. That's correct.
Q. You could do a retro perspective review of those if you wanted to?
A. Correct.
Q. You just haven't done that, for whatever reason. Obviously you're a busy man.
A. No, we haven't done it. It's expensive. And since I don't use the product anymore, I haven't thought of going back and doing it.
Q. So going back to sort of the decision to use the synthetic mesh SPARC sling in your practice, I want to make sure that I understand what you did to satisfy yourself that at that time it was a safe product to implant in women.
A. What did I do? I'm sorry. What was the question?
Q. Yeah. What did you do to satisfy yourself -- as a physician who's supposed to inform patients of risks and complications before using a product in a surgery, what did you do to satisfy yourself when a patient came to see you that the synthetic

Page 75

mesh, the SPARC sling, was going to be safe for them?
A. Number one, I -- the big issue of surgical understanding, this was just a modification of what we already did, so it was -- it was simpler. So that aspect -- we already passed the trocars behind the retropubic down to your finger into the vagina. You already do that with the pubovaginal slings. So there's less dissection, so that I was not concerned about at all. I watched -- AMS provided surgical videos to confirm that. And then I read the IFU from AMS on their -- on the mesh sling. And they have it a little different. They have a tensioning Prolene suture that runs the length of it of how to tension this appropriately, and that was the only difference.
Q. And I understand that's sort of more focused on the surgical procedure. But before you implanted the synthetic mesh into one of your patients who was coming to you, relying on you to tell them about the risks associated with the surgery, I just want to make sure I understand: The only thing you did to satisfy yourself that this synthetic mesh was going to be safe for your patients was to read the IFU?

Page 76

A. The IFU and then the understanding of what I observed at the various different meetings on the TVT presentations because I'm a member of the International Continence Society and SUFU, which is Society of Urodynamics and Female Urology. And so the various different presentations I've seen over the years on the TVT product line -- or at that point it was just TVT.
Q. So you were able to -- you in your mind when you were thinking about the safety of this synthetic mesh for your patients in the 2002 time frame, you in your mind said, well, this mesh looks a lot -- this AMS mesh called SPARC looks a lot like the TVT mesh and because I've seen good results reported with TVT in the conferences that I've attended, I feel comfortable that this mesh is safe?
A. Well, that's one of the components of that.
Q. Okay.
A. Okay? Definitely when you hold it up, it looks identical except for this suture that goes through the AMS one. The outer plastic sheath looks identical. The trocars are different that you pass because it's a different route -- semi-different. So that, with my understanding of

Page 77

the surgical procedure, which is probably the largest component, and then what I heard at meetings and what's available in the short-term studies in the literature.
Q. So there were some short-term studies in the literature about SPARC that you were aware of?
A. No. There was only literature that I -- that I know of, there's only literature that was in -- for TVT.
Q. And just so I make sure that I capture, you know, the things that you relied upon to make sure that SPARC was safe for your patients when you started using it in your practice, you relied upon the company's instructions-for-use document that listed the risks associated with the product; is that correct?
A. Correct.
Q. You relied upon information that you obtained when you went to International Continence Society and SUFU conferences when other surgeons reported on their experience with the TVT product, correct?
A. Correct. And also what I was told by the company reps too because they were involved in the early days with these procedures.
Q. And then information -- a third area is the

Page 78

information told to you by the company reps, the AMS reps, about the product itself, correct?
A. Correct.
Q. And then the fourth thing would be the literature that you were familiar with related to the safety of TVT in short-term studies?
A. Safety and efficacy, yeah.
Q. And am I missing any other categories of information? Did you -- did you talk personally to other surgeons who had used the SPARC product and discussed with them the concept of is this mesh safe to implant in patients?
A. At that point in time, there were nobody to -- there was no one to talk to who had any experience in it because it was brand-new.
I believe David Staskin has the patent on that one. I spoke to him after I started but not prior to. There was nobody who had any numbers to speak of.
Q. Sure. And were you comfortable that the -- when you started using SPARC in your practice, were you comfortable, when you represented to the patients that came to you, that the synthetic mesh was safe for them?
A. At that point in time, from all that I knew

Page 79

and all that I had been told, I thought it was. My opinion has changed on that, though.
Q. And at that time when you told patients about the safety of the mesh -- the SPARC mesh, why was it important to you to look at the short-term studies of TVT that were available? I mean, what -- how did that inform your opinion that it was safe?
A. Well, we were looking at the efficacy. Safety studies -- well, there is no safety study with endpoint -- with TVT at all now. We were mainly at that point in time looking at efficacy. We knew of the complications of death and vascular puncture with the TVT, but this was a different route. So we're going from top down. We have more control. So we didn't think that was going to be an issue. So that's -- we were looking at that literature. It's not perfect. That's all we had.
Q. But you were -- you were -- let me make sure. I'm assuming you didn't mean to say this. You were concerned about the safety of the mesh inside of a woman's body as well, weren't you?
A. At that point in time, from everything we had talked about with -- you know, as far as going

Page 80

around to the Ethicon -- or it's actually Johnson & Johnson tables at our meetings, there was nothing about efficacy, nothing about degradation, nothing about that. We knew an occasional story of vaginal extrusion would happen. But safety of the mesh was not an issue we even considered. I would talk to them about that. Say, what are the issues? And they said, it's good; it's inert; it's great; it's safe. And I trusted them.
Q. But you cared about the safety of the mesh at that point in time?
A. Yeah. We'll be very clear. That's a very good point. By all means I wanted to put in a safe product in the individual, but that information was not provided to me. So I never would have put it in had I known what I know now.
But yeah, safety of the product was a concern. But what I learned in reading the inserts is that it's an inert product; it's safe.
Q. And you satisfied yourself, at least at the time that you implanted SPARC into patients, that the mesh itself was safe for patients?
A. It was -- I have to -- you have to compare that to my fundamental knowledge at the time of the autologous and cadaveric slings and then the

Page 81

ProteGen sling. ProteGen came out into the mid-'nineties. It was a polyester. Horrible problems happened with that. This was not that ProteGen sling. So this was new and I believed it would be safe.
Q. When you started using SPARC in your practice, did you inform the patients who were the first patients to receive it that there was very little long-term safety studies related to SPARC?
A. Yes. I don't know when or how my consent changed over the years. Initially it was -- and we have to be honest with them: This is my first time I've ever done this. However, I've done other types of procedures that are quite similar to this. Here is what we're given from the company. Here's a pamphlet from the company. Here's what they say.
And then over the years as I did more and more, my consent would change. I'd no longer tell them that they were the first patient, obviously. And we'd say, here's the results on our first 50 patients, here's the results on our first 100 patients.
So the consent and my results would evolve over time. But by all means, even now,

which is pretty rare for me to do a first-time procedure, except in 2013 I did one, we're telling them, you're the first one, you're the second one, you're the third one, and here's what happened with the first two, that type of thing.
Q. So when you first started doing the SPARC procedure, you did inform patients -- you informed patients that there were no long-term safety studies involving the SPARC sling?
A. I don't recall using those exact words. Again, safety pertaining to mesh was a concept that evolved later when we started seeing complications and learning about degradation and mesh contraction. At that point in time I was oblivious that those issues happened.
So I don't recall if I told them there are no long-term. I probably told them, much more likely, is we have no long-term efficacious studies with the SPARC. We do have it with TVT, which were relatively short-term still at that point in time. But I highly doubt I told them safety issues with the mesh. I would tell them issues as far as the surgical procedure because that's different.
Q. So when you first started using SPARC, you

would indicate that there were no long-term efficacy studies associated with the mesh, correct?
A. Correct. Again, I can't recall word for word what I said way back then, but I would have to say, this is a new procedure. Again, as far as I know, I was the first in the state to do one, and so there just wasn't data out there yet.
Q. And you would also inform patients that there were -- that this was a newer product and procedure for you yourself?
A. Correct. That was my routine then and my routine now.
Q. Now, why would you tell a patient that -- you know, let me just start with the first point. You know, why would it matter to somebody that there were no long-term studies, even if it's efficacy, related to the mesh? Why would that be an important fact to tell a patient during the informed consent process?
A. Because we're doing a quality of life procedure. Again, it's different than if there's a heart issue where they're going to die. But this is a quality of life.
There is another option available,

the traditional pubovaginal slings which we have long-term data on, and so I'm saying this is new territory. We don't -- because all patients want to know is how long will this last. That's the biggest question they want to know. How much will it hurt. How long will this thing last. That's their questions. So that's when we'd say there is no long-term data on it say.
Q. So you think that's an important fact for a doctor to tell a physician [sic] if that's true as part of a long -- as part of an informed consent process?
A. Just for clarification. You said doctor asks physician.
Q. Sorry. Let me strike that. I have the question in my mind sometimes and it doesn't come out as I've framed it in my brain.
A. I understand.
Q. So I appreciate that clarification.
You would agree that if the fact is true that there are no long-term studies related to a product to be used in a surgical procedure for stress urinary incontinence, that that fact ought to be told by the surgeon to the patient?
A. Yes. You need -- if there is data out -- I

have been presented by companies with data saying hey, there's this study from Europe or whatever. I said -- what I'll tell them is there's a European study. This is what the results of those. With me, I don't know what my long-term results are. You're the first patient; you're the second patient. So I think it is important to be transparent with the patient.
Q. And transparent about the fact that this is a new product or new procedure, right?
A. Correct.
Q. Because the patient may decide, hey, give me the thing that's proven; I don't want to try something new, correct?
A. That can happen, yes.
Q. Or the patient may say, I'm willing to try something new. It sounds like I'm -- my -- the surgeries and the recovery is going to be better and that's more important to me than having some long-term randomized control trial?
A. More often than not, in my personal experience, the patient is concerned about the short-term issues. And they like the idea, and I think this is ignorant, of something new is better. And so there will be a tendency for a

Page 86

patient to want to go for newest, latest thing thinking that's better.

So the patient's opinion about what they want is important to me, but I also have to serve as somewhat of a parent in saying, "yes, but", so I'll explain it.

Q. And so do you feel that the people who received the SPARC sling in a surgery under your care received informed consent?

A. They received an inadequate informed consent.

Q. Okay. And --

A. I'm sorry. I know you -- I paused.

Q. I didn't mean to interrupt.

A. I gave them the best information that I knew at that point in time. Now that informed consent is insufficient.

Q. Now, you still have the contact information for those patients, or at least you have data from medical records, correct?

A. The data would be -- I would have to submit a study, IRB, for it and pay for all procedures like that to be retrieved, which there -- another individual, not in my department, has done that but I have not personally done.

Q. Who is that in your personal?

Page 87

A. That is with the GYN department. My name is on the paper and they're looking at all sling procedures performed at my institution going back however many years. It's roughly, I don't know, it's like 2- or 3,000. That data is in the process of being worked on, but I am not personally one conducting that study.

Q. Who's the lead person on that study?

A. Dr. Linder, L-I-N-D-E-R, in the GYN department. My name is like the fifth author or something, which doesn't mean a whole lot.

Q. When is that set for publication?

A. It's still being in the process of gathered, so it's -- it's -- I don't even think there's a manuscript ready.

Q. But with respect to the patients -- I mean, you now believe that patients does not receive informed consent about the SPARC sling, just knowing what you know now. What have you done to tell the patients who received the SPARC sling about the new information that you have available related to its safety?

A. When the patients come in, we then inform them, because they're usually -- especially in 2011 when the FDA warnings came out, a large

Page 88

number came in. We would examine them, check them out and say, yes, there are long-term issues as far as degradation, contraction, pain. If you're not having a problem at this point in time, we don't do anything.

Q. And do you -- have you seen all of your patients that received the SPARC sling --

A. No.

Q. -- back?

A. No, I have not.

Q. You haven't done any systematic notice to patients who received the SPARC sling under your care to notify them of new information that you believe exists to suggest they weren't provided informed consent, have you?

A. That is correct. I have not.

Q. Do you have any plans to do that?

A. No.

Q. Why not?

A. The main reason is going to be it's a very expensive endeavor to do that, and all of our patients have our contact information. If they experience any complications, they know to call us back, period. They have local care if there's issues. So it's multi-factorial.

Page 89

Q. Don't you think that -- I mean, wouldn't it be important to notify all these patients who received the SPARC sling that they've got a product inside of them that you now believe is not safe for them and you don't use?

A. Well, at the time we were doing this, you know, there was nothing in the IFU to tell me I've got to follow these patients lifelong. So it was never on our radar. That's why we didn't keep any lists of these patients. Now I do.

And so I don't know. I would like industry to help me out because it's a very expensive process to do that. Industry got paid for this. Industry didn't tell me everything. And so I'd like industry to help me out contacting all these patients.

Q. Well, I mean, have you even tried?

A. I've talked to the various different reps. I've explained with the reps, specifically with Mentor and Chris Sellwood, my extreme disappointment, and you don't get anywhere with that.

Q. Have you requested that the Mayo Clinic assist you in notifying your patients about your views on the SPARC sling for those patients that

Page 90

received that particular mesh?
A. I have talked with the legal department about my issues as far as the mesh sling. They drafted up a letter that got sent around to all hospitals owned by Mayo, but we have not specifically gone down the issue of what to do with each individual patient.
Q. So there was a letter that was sent to affiliated Mayo hospitals?
A. Correct. That was back in 2011. And it was a generic, pertaining to all meshes and basically stating that your informed consent needs to be incredibly thorough, and then we printed off what was published by -- I forget which society. It wasn't the AUA. It was one of the others. IU -- not IUTA. I don't recall -- of what a mesh informed consent should be and that you cannot just have a standard informed consent. You need a very specific one with meshes.
Q. And is that something that's accessible to you --
A. No.
Q. -- what was sent?
A. No, I never sent that. That was a meeting with the legal department. They drafted it. They

Page 91

did something -- they sent it out.
Q. Did you -- did you, I guess, provide input into it?
A. Yeah. Well, I was one of eight who did. And then there was a consensus letter that was then sent, but my name was not attached to that letter.
Q. Who were the folks who provided input, other than yourself?
A. The GYN department and urology department, the individuals involved in doing this. It was not a "you should not do this", but you just need to consent your patients very, very well, statement, basically.
Q. Did you agree with the letter that was sent?
A. Yeah. It was -- it was generic. It was just saying, be careful. And it was just following what the -- whichever GYN society came out with their consent. It was just following that, so it was nothing spectacular beyond that.
Q. Now, you do not use synthetic mesh in your practice and haven't used it since 2013; is that right?
A. For incontinence procedures. I have done -- as I recall, since 2013, there had been one patient we did, and I forget why, but it was a

Page 92

unique patient.
Q. Are there other members in the Mayo Clinic gynecological or urological departments that do use synthetic meshes today?
A. The other female urologists in my department chose never to implant them except for a rare situation. So I don't know how many she's done. Maybe 20 over the years. She chose not to because of her -- she was during the ProteGen era.
The GYNs, I cannot speak to how many they do, but they still do the mesh slings. Usually it's the Obtryx -- not usually. It is the Obtryx, I should say.
Q. So the Obtryx is a Boston Scientific product for the transobturator technique, correct?
A. I'm not sure. It's not one I use, but that sounds right. I have no reason to doubt that being wrong.
Q. What gynecologists at the Mayo Clinic do you know use Obtryx?
A. I only know of one who does, Dr. Klingele. I don't know if the other ones do or not, because our practices are not being shared, so it's just if we happen to have a combined case and I happen to see it on there.

Page 93

Q. So let me ask you a little bit about that. I mean, there's -- you've got one physician at the Mayo Clinic, a gynecologist, who uses synthetic mesh as part of his practice to treat female stress urinary incontinence and you've got, you know, Dr. Elliott on the other side in the urologic department that doesn't use it. And the reason you don't use synthetic mesh is because you don't believe that it's safe for patients, right?
A. Correct. There's two of us in urology that don't.
Q. That don't.
A. The other one chose never to from the very beginning and was mocked early on and now the pendulum has swung back toward her favor, which I've subsequently had to apologize to her about. So I did and then chose not to.
But yes, the GYNs. It's not just that ones. It's the other ones too.
Q. Use mesh?
A. Correct.
Q. So how can that be? How can you have physicians who are still implanting synthetic mesh into Mayo Clinic patients and then other very accomplished surgeons believing that that same

product is unsafe?
A. First of all, we're talking about a different product, the Obtryx, which I have done no research on, but let's back up. The blunt, honest answer with that is once I got involved in this litigation, have signed confidentiality agreements, I've seen what's gone on behind closed doors, whether it be with Ethicon and Mentor and what they knew prior to release of the product. That I cannot tell them. I cannot tell anybody at Mayo and I have not told. I regard that as a very strict, and understandably so, issue. So they don't know what I know, is my basic answer.
And they've dealt with the complications. They've dealt with some of my complications of meshes so they know them, but they don't know the full extent.
Q. What is it that you would disclose to them? I mean, these documents are all non-confidential. They've been admitted at trials, and -- there's been three ObTape trials. There's been, you know, various unveilings of documents along the way. I mean, what is it that you can't tell them?
MR. KREIS: I'll object just to the extent that this doctor doesn't know what is or

isn't confidential. In fact, many of the documents that we had in our recent punitive damage proffer were not part of early or current litigation trial, so those are still under confidentiality. So we haven't had a conversation with Mr. Elliott in terms of what is releasable or not. But if you'd like him to -- us to share that information with him, then we certainly can.
BY MR. LEWIS:
Q. Well, let me get to this point, I guess, Dr. Elliott. I mean, we're talking about patient safety -- Mayo Clinic patient safety, okay? That's the topic right now. And you are aware that physicians at the Mayo Clinic, gynecologists, are implanting meshes in Mayo Clinic patients, right, and you believe in your mind that that product is unsafe -- that those mesh products, all of them, because you don't use any of them, are unsafe, right?
A. Well, not all meshes are created equal, like Mentor or TVT or Aris. Those are different -- they have polypropylene, which has its own inherent problems, but there's different levels of complications with those. I do not know and have not been involved in any of the litigation with

Obtryx. I don't know any of the internal data.
I am also exquisitely sensitive or fearful, let's put it that way, to disclose anything that I've learned because I don't know what is and is not. I can just see, if I say something, a lawyer freaking out, and I don't want that so that has not been discussed.
Yes, patient confidentiality -- or patient safety is very, very important, but also like I can't cross that line.
Q. But I mean this is -- you're not involved in any Obtryx litigation, are you?
A. Correct. And I don't know of any of the Obtryx internal data so I can't disclose anything there.
Q. There's nothing that you know about Obtryx that's confidential, right?
A. That is correct.
Q. You know that Obtryx is one of these macroporous woven meshes, just like TVT, just like SPARC? I mean, they're all the same.
A. No, they're not all the same, and I've not done any research on it, so I can't say. Again, I don't go where I don't have information.
Q. I mean, do you believe that there are certain

synthetic meshes that are safe for use in the surgical treatment of female stress urinary incontinence?
A. I think there are certain mesh slings that are safer. There are none that are inert.
Q. Which ones are safer?
A. I think in my hands, the Aris SP or the Aris product, whether it be transobturator or suprapubic, was safer. And in my experience, because the edges are this woven, non-welded, it did not stretch. The pore sizes remained relatively stable during implantation and I felt it was a safer product.
The Monarc and the SPARC I stopped using specifically because of safety because the adapters were bulky, tearing the bladder. The mesh was springy. It sawed through the tissues. It would roll. All those type of things, so I stopped using it. The GYN department chose never to use that. They went down a different route, and so they used the Obtryx. So, again, I have no -- I've never seen one. I've never even seen the box or looked into it. That's why I'm not going to venture into that territory and let them choose -- or tell them what to do.

Q. Sure. But I mean -- let me back up. You care about patient safety, don't you?
A. Yes, I do. And the ones that I can influence, which are my patients.
Q. But I assume you would care about the safety of all Mayo Clinic patients, wouldn't you?
A. Yes, I do. And "all" cardiac patients and I don't get involved in the cardiac care. This is a different department doing implants with highly qualified surgeons. We talk about mesh and mesh complications and what to do but, again, I'm not going to tell them what to do.
Q. And what interaction is there between the uros and gynos at the Mayo Clinic specific to synthetic mesh?
A. Oh, it will just be casual conversations in between cases. Nothing organized.
Q. Has there ever been any -- other than the letter that was sent by the legal department, has there ever been any discussion -- internal discussion at the Mayo Clinic about the safety of synthetic meshes and whether there should be a policy change at the Mayo Clinic?
A. No. It was only with Mentor years ago that happened, an ObTape product, because the GYNs took

care of my patients which was subsequently written up.

But the other ones, no. It -- except for the pelvic organ prolapse kits where everybody was on the same page, that they should never be used and never were used in my institution.
Q. So let's talk about the pelvic organ prolapse kits for a second. How did it come about that there was a policy decision not to use those kits at the Mayo Clinic?
A. There was not a coordinated decision: Let's sit down, let's do this. All of us -- all six or seven independently decided we're not going to take care of this -- or we're not going to implant these.

I personally, when that first happened, didn't see the reason for it. My repairs were working. I didn't see the reason to use all the extra excess money for that. GYNs had their other reasons.

And then we started seeing the complications come in around 2007 or '8, and then we started talking about it because there was a case here and there. And then the -- then there

was never a formal policy: We do not implant these. It was all just, we weren't implanting them anyway.
Q. But was there a meeting or a discussion or something that happened where everybody sat in a room and sort of talked about it?
A. No. There was a decision made by the legal department to send out letters to all institutions owned by Mayo concerning the consent.
Q. And that was that consensus document we talked about?
A. Correct.
Q. With ObTape, what was it you -- you indicated that there was some sort of decision not to use ObTape --
A. Yeah.
Q. -- at the Mayo Clinic group?
A. I was the only one using it -- I was the first one to use it in the state and possibly the first one to use it in the United States. That's debatable. So the GYNs were not doing transobturator at all. That was the first one to come out transobturator. So I was doing it. I did 105.

And then unbeknownst to me, some of

my complications that I didn't even know about were going to the GYN department, that they would either inform me of or wrote up papers, or I found out about one recently because I had to get -- was going to give a deposition, along with the GYNs, about an ObTape complication. This was about six or eight months ago. It ended up settling out of court.

I found out about it. I looked up the patient's name, realized that the GYN department had operated on her and then the GYNs had written it up, and that's the Occhino paper, O-C-C-H-I-N-O. And that's my patient and I didn't even know about that until, again, six, eight months ago.
Q. But with respect -- and is that the only paper that you're aware of that's been written up on outcomes for your ObTape patients?
A. Correct. Now -- now, again, there's another Mayo paper, Bobbolo, Bobbalu (phonetic), something like that, which was an ObTape. I don't know where that one came from. I don't know if that's my patient or not. I mean, there's a decent chance it was mine because I was the largest implanter here, but I can't guarantee that. The

Page 102

only one I know of is the Occhino paper.
Q. That's your patient?
A. That is my patient, which that paper came out in like 2010 and I didn't know about it until this year or late last year.
Q. That wasn't shared with you by the gynecologists that published it?
A. No.
Q. So the decision to use or not use ObTape, you were the only one who ever used it?
A. Correct. And then they wanted to know what my results were -- this is way back in 2004 -- because they were incredibly interested in a transobturator sling because it didn't exist at that point in time. TVT-O had not come out yet, and they wanted to know my results. And my opinion about it changed dramatically from -- the initial description of the surgery was I was thrilled with it, and then as time went on, that year to a year and a half when I started having the complications roll in. So that's when there was an informal discussion of saying, I've stopped using it.
Q. And that was your personal decision?
A. Correct.

Page 103

Q. No one else was using ObTape at that time?
A. There were a couple chief residents using them. One who had three erosions out of five patients, and he came to me after he did my service, wanting to know what was going on.
Q. What doctor was that?
A. Dr. Dora, D-O-R-A.
Q. All right. Anybody else?
A. Not that I know of.
Q. Have you ever gone back and looked at what the outcomes were for your 105 patients?
A. Yes. As far as I know -- and this was tabulated in roughly 2007 and this is in my report somewhere -- of the 105 patients that I did, I had nine vaginal extrusions. Then in 2014, I believe, seven years after implant -- or eight years after implant -- and, again, I'm not sure; maybe it's 2014 or 2012 -- another one of my patients came back with a vaginal extrusion. I had three buttock abscesses, requiring emergency surgery. And I know -- I talked to two physicians -- these are not my experience -- one in Arizona and one in Pittsburgh who called me up, of their bizarre findings, because we had never experienced this before. When the patient called me up from

Page 104

Oregon -- that was my implant -- complaining of buttock pain, I'd never heard it before. I told her just to go to your local doctor because I thought it was something else. She decided to come fly to us. We got a film and it showed this huge abscess in the gluteus maximus, and we immediately took her to surgery.
Q. So of the 105 patients that you implanted with ObTape, you're aware of ten extrusions?
A. That's correct. I am aware of ten, so I don't know if there's more because the majority of patients I don't see back, so the number is not going to be less than that.
Q. Sure. So you're aware of ten. And of those ten extrusions, there were three abscesses?
A. The three abscesses were separate.
Q. On top of the extrusion?
A. On top of it.
Q. So there were -- so there were abscesses -- so you count the extrusions as non-abscess extrusions?
A. Well, no. Actually -- that's a very good point. I don't recall if those had extrusion or not -- those three buttock abscesses. I don't recall that, and so I don't know if I've included

Page 105

those in the ten known extrusions or not. So we can either say it is or isn't. I just don't know. I didn't tabulate that that accurately.
And that was all informed -- I told Chris Sellwood all of those because he was very interested in our results and early on we were exchanging e-mails about it, and then -- they knew all about that. And then I think when we had our third -- second or third buttock abscess, I said, that's it; I'm never using this again.
Q. Okay. Now, do you still -- do you still maintain an e-mail address with Mayo Clinic?
A. Yes.
Q. And is it -- have you ever gone back and searched for e-mails that reflect communications with Mentor about ObTape?
A. I've never done that. And the e-mails get deleted after a certain period of time. They get stored and then deleted, so I don't have access to them.
Q. What period of time would that be?
A. That's a good question. I have no idea. But they do it for storage, saving space. We have the ability to archive them, but you have to do that proactively and I didn't do that.

Page 106

Q. Did you ever create a folder that was a Mentor folder or ObTape folder?
A. No.
Q. Is your e-mail address still Elliott.Daniel@mayo.edu?
A. E-D-U.
Q. E-D-U?
A. Correct.
Now, can we go off the record for just a second.
Q. Yes.
(Off the record from 11:12 a.m. until 11:13 a.m.)
MR. LEWIS: We just had a discussion off the record. We agreed to a designation of Dr. Elliott's e-mail address as confidential for purposes of the deposition.
BY MR. LEWIS:
Q. All right. Let me try to map out this timeline again.
So SPARC in 2002, 2003.
When did you first start using -- when did you introduce ObTape to your practice?
A. It was in the fall of 2003, and I think in my report somewhere I give you a semi accurate date.

Page 107

Maybe I don't. Oh, approximately October 1st of 2003.
Q. Okay.
A. That's a guess, but it's fairly accurate.
Q. So between 2002 and when you started using ObTape in 2003, what percentage of your practice would have been SPARC?
A. Almost 100 percent. There would be exceptions for complicated reconstruction or redo -- redo surgeries, but otherwise it would have been SPARC.
Q. So in that time frame, you almost completely went away from cadaveric pubovaginal slings and autologous pubovaginal slings?
A. That is correct.
Q. Why did you make the switch from SPARC to ObTape?
A. Two things. Number one, it's a different procedure going through the obturator foramen, which was revolutionary at the time.
But the biggest driving reason is the complications we had with SPARC. As I mentioned, the connectors -- you were having these bladder tears. We were -- roughly 5 percent of our patients, we were tearing the bladder. Had to

Page 108

have -- imagine with catheters, because you pull this big connector through. Even after we did a cystoscopy, no bladder injury. You pull a connector through and it's so bulky, it just tears through the fragile bladder. It was an unacceptable complication because the mesh was exposed, everything.
Number two, tensioning of the SPARC. It rolls. It curls. Just like a taco, roll up like that. I'm just -- roll up like a taco. And we had trouble tensioning it, and then you would have this band of mesh in there, so I did not like it. And we were searching for an alternative and that's when I was presented by Mr. Sellwood of the ObTape. So it just happened to be we were probably going to be switching back to the pubovaginal sling and then coincidentally, this ObTape -- the transobturator route was presented to me.
Q. So at the time that the ObTape option came to you in 2003, you were looking to move away from SPARC; is that right?
A. Correct, yes.
Q. And chiefly due to intraoperative complications and difficulties with the surgery.

Page 109

Is that fair to say?
A. That's -- that's correct, yes. We were wanting -- we wanted an outpatient procedure without those complications, so we were looking for something else.
Q. So what did you do to satisfy yourself -- in the fall of 2003 when you decided to use ObTape in your practice, what did you do to satisfy yourself that ObTape was a safe product for your patients?
A. Very good, because I remember this well because, again, I was concerned about the ProteGen, so I talked -- all this conversation was through Mr. Sellwood. And the porosity of this thing looked thick. He said, no, there's a study, 9,000, 10,000 patients from Europe showing it's working; it's great. So I said, okay, that's good.
He showed me the IFU, or the PID as Mentor calls it, which there was no issues, no long-term problems mentioned. It all looked great.
He showed me a surgical video of it -- of the transobturator route because that was an incredibly new approach to dealing with this. I watched the video and said, that's a simple

Page 110

procedure to do.
I at some point in time -- and I don't recall the chronology of this -- I went to Vegas -- no, not Vegas -- Phoenix. Carl Klutke was putting on a course in Phoenix -- an ObTape course, and they had a big pamphlet on it -- not big pamphlet. A big folder of everything. So I did that.
I think that's all I did with that. But there was no literature on it at all.
Q. Right. So the folder -- do you recall getting a DVD that explained the surgical technique?
A. I don't recall that. I do recall exactly where I was standing when Chris Sellwood put it in his computer, laptop, and played it for me. I don't recall if I ever got the DVD or not.
Q. Okay. And then the session that you attended in Phoenix with Dr. Klutke, that was like a transobturator technique training session?
A. Correct. And as I recall, Klutke was in charge of that and there was a bunch of other physicians. He may not have been the lead person. That's just the one I remember.
Q. And as part of that training session, did you

Page 111

receive a folder of information?
A. Yes.
Q. Do you still have it?
A. No. Unfortunately, no, I don't. It was a large folder, a lot of data, a lot of -- and everyone's slides who spoke, and that has been thrown away years and years ago.
Q. Did you attend that Phoenix training session prior to implanting ObTape in your patients?
A. I don't recall. It was hot. That's all I remember, but then that means Phoenix is always hot. It was actually at the Phoenician. I mean, I remember where we were going because it was hot. So, again, it could have been before. It could have been right after. I don't recall.
Q. It was in and around the time that you first started using ObTape. Fair to say?
A. As I recall, yes. To learn surgical techniques, pearls, all these types of stuff, the data that was available.
Q. So to satisfy yourself that ObTape was a safe product for implantation in your patient population, one of the things that you did was look at the product insert, correct?
A. Absolutely, yes. And I asked Sellwood for

Page 112

that.
Q. You specifically requested it?
A. Absolutely. He gave it to me. He also, you know, then I think verbally told me about 9,000 or 10,000 study patients.
But yes, the PID was given to me. I don't have it, obviously. And then the videos on the surgical procedure -- or DVDs at that time.
Q. I want to ask you about that. I mean, so the product insert is a document that is contained in the package with the product itself when you receive the product to implant into a patient, right?
A. But it was before -- before the procedure. Sellwood presented to me -- outside the operating rooms at St. Mary's Hospital, he said, we've got nothing new. He said, transobturator. I remember very clearly. Through the obturator foramen? No one has ever done that before. I said, I don't think this is going to work. He said, no; look at this video. He showed me the video. And he said, here's the product, so he had the actual -- a sample, and then the PID along with it. And so that's what I looked at, all three at that point in time.

Page 113

Q. So I just want to be clear about this. Mr. Sellwood presented you with a hard copy of the product insert outside the operating room, outside of a package of the product, he presented that to you prior to you using the product?
A. Correct. He had kind of an introduction packet, let's call it that, where he had -- he showed me the device. And remember, as soon as I saw it, I thought about ProteGen. So I asked him -- because ProteGen was bad, a horrific product. He said, no; this is different. 9,000 patients, 10,000, whatever that study was. It's working great, has great efficacy, everything. So I took it at face value. Here's also the product insert, and he maybe gave me some other brochures or maybe told me about the other meeting -- the Phoenix meeting. I don't recall that. And then we watched the video there on his laptop of the procedure. I watched it once and said, that's brilliant, that transobturator.
Q. And the reason why I'm asking you these nit-picky questions about the product insert, just so you know -- not Mr. Kreis -- other lawyers have presented in this ObTape litigation that the product insert is only available at the time of

Page 114

the surgery in the -- in the surgical field in the surgical room?
A. I would disagree with that -- well, no. I agree and disagree. I agree if I want to get a product insert -- I mean, now I can just -- you can just pull it offline, but then you couldn't. I'm sure you couldn't. Well, I didn't try either.
You need to get the product and pull it out. But this was coming from the rep, who is the regional rep -- not just Rochester, Minnesota, but the five-state region, so he's more powerful, came to me because they wanted me to do the procedure so they can then say, the Mayo Clinic approves this procedures. It's a lot of good marketing, which I'm aware of that. I'm not naive. So --
Q. You're not naive? Sorry.
A. I am not naive that the industry is going to want to use --
Q. Sure.
A. And I don't know the extent of what they -- I've had industry say all these things that I've said and I know I haven't said it, but that's beside the point.
But Sellwood would more likely than

Page 115

not have access to stuff that I'm going to be asking for and he wants to sell this product to me.
Q. And you wanted to see the product insert?
A. Absolutely. I wanted to see the product insert, I wanted to see the product, and I wanted to see the surgical video.
Q. You're not looking at the product insert for the first time when the patient is under anesthesia?
A. I will show the residents when the -- each resident comes on my service, when we're doing a relatively new procedure, I have the residents go over it because -- as a practice.
Now, if it's a procedure that's been around forever -- for example, the artificial urinary sphincter made by AMS, which is now owned by Boston Scientific, been around since 1972, Mayo is the world's largest implanter, I don't have them go over that.
But a new device, I have them go over, whether it be -- whatever it is.
Q. Ahead of time?
A. No. In the OR because we can't get it otherwise, unless I save it from a previous

Page 116

procedure.
Q. But you yourself, when it came to the ObTape, you viewed the product insert before you performed the surgery?
A. Correct.
Q. And you asked for it -- you asked for that product insert or otherwise Mr. Sellwood had it with them?
A. Yeah. I don't recall if I asked for it or not. It was given to me. It was provided to me.
Q. And that was something that you wanted to see before you started implanting --
A. Yes.
Q. -- ObTape?
A. Yes.
Q. Fair enough.
A. Again, because it's a new procedure. I don't do that for a procedure that I perform 1200 of.
Q. Understood.
Well, in that product insert, you do recall that Mentor said that one of the things that has been reported is erosion of the device, right?
A. Well, we have to be very careful now how we define "erosion" versus "exposure", okay? This is

Page 117

just for clarification of this purposes.
Yes, they do say erosion. Erosion means going into an organ -- another organ, urethra or bladder. At that point in time, the terms were interchangeable. So yes, in their PID, they talk about -- well, I'd have to pull out the PIDs to make sure it says it exactly. It said there is a very rare risk of vaginal erosion, or which should be correctly termed "exposure".
Q. You understood that to mean "extrusion"?
A. That -- you're absolutely right. I just want to be clear because it's been up -- people argue about it, so I'm using the terms. We're communicating.
Q. Sure. It also indicated that infection was reported. Do you recall that? I mean, I --
A. Yeah. I'd have to --
Q. I can pull out the product insert. And if you prefer that, that's fine.
A. I have one here. I don't know if we want to admit it. Well, it says Exhibit B. I don't know why it says that. This is something you guys sent me and I copied off.
MR. KREIS: John, for the record, this would have been from a prior deposition.

MR. LEWIS: Okay.
MR. KREIS: And it's Rev A.
MR. LEWIS: And I don't need to mark it. I don't think there's any dispute about what the adverse reactions reported are in there, and what it says, it says.
THE WITNESS: And it says -- just so we're clear, it says it can trigger an existing infection. I don't think it says it can be responsible for an infection. It's right down there.
BY MR. LEWIS:
Q. Then it says, "The following events have been reported very rarely," and then it has the three bullets.
A. I'm sorry. Yes, it does say "infection" there, yes.
Q. So infection, vaginal erosion, and urethral erosion is also noted there?
A. Yes. It should be with normal, or modern nomenclature, vaginal exposure. Urethral erosion is correct. And then infection, yes.
Q. When you reviewed the product insert, did you remember at that time seeing those potential adverse reactions and did it have an impact on

you?
A. Absolutely it did. I saw that, and my frame of reference at that point in time is going to be the TVT and, much more likely, the SPARC, okay? That mesh, that polypropylene. Vaginal erosion -- or vaginal exposure happened in my hands 2 to 3 percent, roughly. That's a guess -- very much of a guess. Urethral erosion never happened. Infection, I had one patient out of several hundred with a superficial cellulitis which was with topical antibiotics.
Q. With the SPARC sling?
A. With the SPARC sling, correct.
So that was my frame of reference. I saw that and thought that's no big deal at all. We treated those. No sequelae.
Q. And you understood that the ObTape had potential adverse reactions that did not exist with the autologous pubovaginal sling?
A. Well, it's a foreign body and it's a -- it's a polypropylene, so I put it in the same reaction that would happen with a TVT or a SPARC in my hands.
Q. Fair enough.
So the product insert was one of the

things that you reviewed prior to using ObTape. The surgical video was one of the things that you used prior to using ObTape. And then you recall verbal discussion from Mr. Sellwood about the number of patients who had been -- who had received ObTape, and the product was performing well?
A. That is correct. And the reason why I remember it carefully -- or well is 9,000 is a gigantic number. You're lucky if you get a study of 100 or 200 patients. 9,000 is an astronomical study, and he says they're doing well. So I said, okay, good. If that many patients have had it and they're doing well, that's great.
So it was -- it was -- if he gave me a number of 100, I'm not going to remember that because that's just like everything else.
Q. And do you have an understanding today that, in fact, there were actually more patients than that who had received ObTape or its prior generation, EuroTape, prior to launch in the United States?
A. I don't know the numbers on EuroTape. I know it was used for a while, but I've never, that I recall, seen the numbers. And then I know ObTape

was introduced and, again, I don't recall seeing those numbers, other than this 9,000 I was told about.
Q. And, again, you recall that being a verbal discussion at that time?
A. Correct. I never saw that paper. I just said, well, what are the studies out there? And he said, well, there is this paper, 9,000, and he says it's working great.
Q. He said there was a paper?
A. I don't recall. That's too specific. I don't recall. It's been done in 9,000 and here are the results.
Q. Okay.
A. So, again, I don't think there was an actual paper because I would have asked for it.
Q. That's what I was going to follow up with you.
Did you ask for written materials that reflected the performance of ObTape prior to using it?
A. Very good question. I always -- well, first of all, now I have zero interaction with reps. They don't even get into my office. They don't talk to me. They can't e-mail me, nothing.

Because they're like used car salesmen.
Then I was different. And with Sellwood it was different. Sellwood was a nice guy. I would ask, what have you got as far as literature? I don't recall what the answer was. Whatever it was, it satisfied me at that point in time. Now, that would not be now, but that satisfied me then.
Q. And you don't recall what you received?
A. No. Just what I've already --
Q. What you've already said. Okay.
A. Yes.
Q. And then you received a packet of materials from the Phoenix -- one of the other things you did at or around the time that you first started using ObTape was to attend a session that was led by Dr. Klutke in Phoenix?
A. Correct. I'm pretty sure it was the Phoenician in Phoenix.
MR. KREIS: John, when you have a second.
MR. LEWIS: Yeah.
(Recess taken from 11:31 a.m. until 11:42 a.m.)
BY MR. LEWIS:

Q. I think we were talking a little bit about the information that you used to satisfy yourself that ObTape was safe prior to using it in your practice. I believe I've covered four things. I just want to make sure that -- did you -- prior to using ObTape in your practice, did you review any abstracts, literature publications, related to ObTape or its European predecessor, EuroTape?
A. I don't recall what was given to me. I may have, but I just don't recall. I would ask for it and if something were there, I would have reviewed it.
Q. Do you recall getting any slide decks or PowerPoint presentations about ObTape or the surgical procedure, transobturator tape, as part of your diligence before using ObTape in your practice?
A. The meeting I went to in Phoenix, they gave a big handout with a lot of slides and then, of course, attending the lectures. I don't recall if Chris Sellwood gave me that, but I don't think he gave me those, though.
Q. You used ObTape between the fall of 2003 and what time frame?
A. It would have been -- I don't know exactly.

It would have been the end of '04, early '05 because, again, I did roughly 100, 150 slings a year at that point in time, and I stopped at 105 because that's when the complications were coming in. And so I'm just -- this is on recall, so I can't tell you the exact time frame.
Q. Between the time frame of the fall of 2003 and when you stopped using ObTape at the end of '04, early '05, what percentage of your practice would you say you did ObTape?
A. As far as -- well, I think what you're asking for is for female stress urinary incontinence.
Q. I'm sorry. Correct.
A. And that would have been nearly 100 percent.
Q. And is there a way that you could look and determine when you actually placed your last ObTape patient?
A. I would probably be able to find that information. Again, that would require I would have to go -- I would have to submit an IRB form to get access to patient records and have our surgical people pull it up. That information would be able to be found -- the last one I implanted.
Q. And just sitting here today, you haven't done

that?
A. No, I have not.
Q. Do you have a recollection -- I mean, I'm trying to find some reference points to when you switched, and so I'm trying to think of -- did you start using another product instead of ObTape?
A. I went back to the SPARC. And then somewhere in there AMS came out with their Monarc, which is their transobturator sling, and so I used that for a short period of time until AMS came with their with Aris and their transobturator Aris.
Q. Aris would be Mentor and Coloplast?
A. Mentor and Coloplast, yes.
Q. And when Aris came out -- and I'll just reference you, that was roughly May of 2005 in the United States, just to give you a reference point -- do you recall whether you used Aris pretty soon after it came onto the market or not?
A. I was -- I was still very much in conversation with Chris Sellwood because I liked working with AMS [sic]. I felt --
Q. You mean Mentor?
A. Yeah. What did I say?
Q. You said AMS.
A. Yeah. I'm sorry. I don't like working with

Page 126

AMS. And you can quote me on that one. I don't like them.

The Mentor people, at the time I felt that they were good people and I enjoyed working with them. Now my opinion has changed as far as the data that I was given, but then I liked them and I wanted to continue to work with them if they had a good product. So I very clearly remember telling Chris Sellwood, this ObTape is bad; I've had unacceptable complications; I'm switching over to AMS. It was a big deal for me.

And then he informed me -- I don't remember the date, but I remember when he informed me that this Aris was come out. And they call it Aris and Aris SP, so it was kind of confusing on their names. And I would have used it probably very rapidly because, again, as I mentioned earlier, I did not like using the AMS product because of those connectors, and it was worse for the operator because you'd pull it through this canal and it tore. We had patients with a horrible amount of pain. So it was a big deal for me to switch over back to at that time, when Coloplast or I don't know if it was Mentor -- I thought it was Coloplast.

Page 127

Q. So Mentor sold Aris -- just to kind of reference you, sold Aris beginning in May of 2005. And then in March of 2006, that's when Coloplast purchased Mentor and then continued selling the Aris product line. Many doctors have trouble orienting themselves because it was pretty seamless. Most of the people came over and they just sorted of picked up the product line. It was ongoing at that time.

A. Correct. And I do remember when that sale happened because they asked me to come up there to give a summary on stress urinary incontinence, which that has a Bates number attached to it, the lecture I actually gave to them, summarizing my ObTape experience, which has just mirrored what I've told you today, and what my experience of the other products were because they wanted to have a semi-honest opinion of what's gone on.

Q. So would you think that sometime in 2005 would be a good -- and I'll just kind of roughly put it 2005, somewhere along there, you went back away from SPARC and Monarc and started using Aris at that time?

A. Yeah. Again, it was -- I did 105, and I'm going based upon me doing 100 to 150 per year. I

Page 128

started in the fall of '03. So somewhere in there is when it happened. So late '04, early '05.

Q. And then you went to SPARC and Monarc for a while?

A. For a short period of time, and then swapped over to Aris, and then had not changed until I stopped in 2013.

Q. So Aris was picked up. And then you used Aris until 2013?

A. Correct.

Q. And during the time that you used Aris, what percentage of your practice was Aris for female stress urinary incontinence?

A. Well, the number of slings that I did progressively decreased from that time, so -- but the percentage-wise for the run-of-the-mill, straightforward, you're probably looking at 95, 99 percent, were going to be the transobturator or the suprapubic Aris, with a few complicated reconstructions being the autologous or cadaveric. That was always the fallback. And then beginning in 2011 with the FDA warnings and patient awareness increasing, that's when the pendulum started swinging back towards autologous.

Q. So at least through 2011, perhaps 90 percent

Page 129

or so of your practice?

A. That would be fair, yeah, 90 percent or higher.

Q. And then in 2011 you would say maybe -- it would eventually reduce between 2011 and 2013 to zero?

A. Correct.

Q. And did you attend the FDA panel hearing on mesh?

A. No. My comments with Public Citizen -- they're the -- Michael Carome, C-A-R-O-M-E, contacted me in 2010 because I had made -- given lectures anti -- well, against mesh and somehow he had picked up on that and then wanted me to give an opinion for the FDA hearing. I did not attend but my comments were supposedly -- in fact, I know they were read, but I was not there.

Q. And those are comments that were -- that were a letter or what -- what exactly -- when you say "comments" --

A. Yeah. You can actually -- if you just search my name and Public Citizen, the actual document will come up. And it was written on my letterhead. It's a full page long just summarizing my opinions on meshes. There was

Page 130

another doctor from St. Louis. I'm blanking on his name. And then Michael Carome had a long dissertation on meshes. But mine was just one page. But that is retrievable. I don't have it with me, but it's easily retrievable.
Q. Now, let me ask you about the Aris product for a minute. What was your -- what was your patient outcomes with Aris, roughly speaking?
A. The adapters -- let's talk about inter-op versus long-term.
Q. Sure.
A. Inter-op, remember with the AMS product I hated because they had large connectors tearing in the obturator foramen and tearing the bladder, which is unacceptable because of patient pain.
So the adapters -- or there is no adapter with the Aris, so they eliminated that, so you had a very small profile going through.
Surgical procedure is identical otherwise.
We still had bladder perforations which happened with the suprapubic or retropubic approach. That was around 10 percent. So that was an unacceptable problem, from my angle.
Vaginal extrusion rate was fairly

Page 131

low that I can think of. We've had 2 or 3 percent with the transobturator route.
We've had problems with dyspareunia because you'd have mesh at the sulcus, which is -- the vaginal sulcus bilaterally. So it makes you modify how you do the procedure, take extra-deep bites.
We had some scarring and things. It was relatively -- overall experience, relatively minor. Never had an infection -- never had a wound infection with it.
Q. Okay. So your relative experience with Aris you would say was -- would you call it positive?
A. I would have -- the best way to describe it is it was the least of the evils. It was -- it was less mesh extrusion, less dyspareunia, less bladder perforation, less obturator foramen pain or groin pain. I didn't have any infection, no cellulitis, no vaginal breakdown that I know of. And this is -- again, the experience with Aris, let's just say 500, thereabouts. That is a guess. So, again, I know I'll keep saying that over and over and I understand you know that, but just so we're clear, I'm guessing. Somebody could pull out a number and say 300. That could be 600.

Page 132

Roughly 500. We did not have those problems that I saw with the AMS product, definitely with the ObTape.
Q. So would you agree that Aris was the best performing synthetic sling that you've ever used personally?
A. Framing it in that way, not to condone it, but it was -- I had the least complications with it. Now, I still had the dyspareunia, which was -- it's a pain to deal with it. It's very difficult. We can't fix it. But, again, comparing it to the other products, it was the least.
Q. And you stopped using it because you stopped using all synthetic meshes in your practice to treat incontinence?
A. Yes and no. I stopped using it because I was still having complications, okay? And patients were coming in refusing meshes, adamant against meshes, because this is when the FDA came out with their warning. There was a huge uproar about it, but I -- we were struggling for an alternative. Patients wanted an outpatient procedure that was non-mesh. At that point in time, it did not exist and we came up with one.

Page 133

Q. And what one is that?
A. Transobturator autologous sling.
Q. And did you start using transobturator autologous slings -- or I guess autologous tissue, right?
A. Rectus fascia, yeah.
Q. So a pubovaginal sling used through the transobturator route?
A. Well, no. I mean, the pubovaginal is like saying a Chevy. The Transobturator is like Ford. They're different. They're different procedures.
So we're using a small sliver of autologous tissue, compared to -- for a pubovaginal sling you use a 2-by-12 centimeter long piece of fascia, a large piece of fascia. We are using a one-and-a-half centimeter wide by 5-to-7 centimeters long. We have modified -- we continue to modify the procedure. So we're harvesting a much smaller piece of tissue so there's less pain, and then we're delivering it through the obturator foramen, so that now we're avoiding the complications that can happen when you go through the belly. So it's kind of a modification of the two, a hybrid of the two. And we've published that now three times, I think --

Page 134

three different studies which are out there.
Q. On the performance?
A. Autologous transobturator, yes. I think it's in the -- it just came out in Urology, which is the Gold Journal, which is our semi-long-term. We're still calling it short-term even though we have a year follow-up. We have a surgical video which is in International Urology Journal. And then a preliminary early surgical description under surgical techniques in Journal of Urology.
Q. And are you teaching or otherwise demonstrating the surgical procedure to other surgeons at this time?
A. To just residents.
Now, we have -- we have published the video so it's out there through the International Urology Journal. It's retrievable there. Somebody can watch it, which is actually great. And then we've spoken at multiple different meetings on the results and then the journal articles. So if you call that teaching, then yes, but it's not like we're bringing individuals into my institution to show them how to do it, but -- besides residents -- my own residents.

Page 135

Q. Do you know of anyone else who's using that procedure?
A. Yes, in Europe. A doctor in London who I speak to came up to me at a meeting says he's done it and had it work on a very complicated patient, which is good news.
Q. Is that your sole -- is that the chief treatment that you undertake for women who now present to you with stress urinary incontinence when they need a surgical procedure?
A. Yes and no. The most common surgical procedure I'm performing are going to be on complicated reconstructions who have multiple surgeries elsewhere. That is still going to be the pubovaginal sling. So for those complicated redos, it's the old-fashioned autologous sling.
For the new patient who's coming in, first-time treatment, run-of-the-mill stress urinary incontinence, then the autologous transobturator is my go-to procedure, with a full consent, et cetera.
Q. So first-time treatment, you typically go with --
A. Transobturator autologous sling, yes. So instead of in the past going with the

Page 136

transobturator synthetic, now I'm going with the transobturator autologous.
Q. Is that an outpatient procedure?
A. Yes. We've had one or two patients stay overnight. Usually it's when we're doing a combined prolapse repair.
Q. Is the procedure itself relatively -- I mean, it's a smaller piece to handle, but is it relatively the same procedure as you would place synthetic mesh?
A. Correct, except for the harvesting of the tissue on the belly. We do a 5-centimeter incision on the belly and harvest it, so there will be more discomfort with that. However, we are following our patients at three months and a year with pain surveys to see if they have any persistent pain. And so we are not seeing that at all, which is in our published data.
Q. And you still have the -- essentially the three incision marks? Two on the groin area and then one in the vaginal wall?
A. Yeah. The vaginal incision is the same length as the synthetic. We go slightly deeper into the tissue, just because we want to kind of make sure we get a better snug fit. On the

Page 137

outside of the vagina, on the labia, we'll make a 5-millimeter to 7-millimeter incision which will be slightly larger than the synthetics. Cosmetically, pain-wise, there's no difference there. The main difference there be the abdominal incision, which will be 5 centimeters, that you don't do with synthetic.
Q. The abdominal due to the harvesting of the tissue?
A. That is correct.
Q. Let me ask you this: Why hasn't anybody thought of this before you?
A. We had a problem. Patients refuse -- patients coming in with stress urinary incontinence who were adamantly refusing anything synthetic put in their body, and so we had a problem. I knew the mesh literature. I didn't like putting in meshes. And so we said, well, why don't we just do this combined. So all it is is doing is combining the pre-existing knowledge, putting them two together. It's like saying didn't someone come up with the iPhone before they did? I don't know. I mean, it's just we had a problem, we thought about it, and we came up with this option.

Page 138

Q. Would you agree that the treatment for female stress urinary incontinence has evolved over the course of time that you've been practicing in the area of urology?
A. It's changed tremendously. When I started in '93, it's gone through multiple different waves of pubovaginal slings, then synthetic slings, then transobturator slings, and now the pendulum is swinging away from anything synthetic. And so yeah, it's changing and five years from now it will probably be different.
Q. Would you agree that one of the goals that's always been in existence -- for the treatment of female stress urinary incontinence, one of the goals is to have a treatment that cures incontinence?
A. That is safe. That is correct. That it cures incontinence, but because that's a quality of life problem, it has to be concurrently safe.
Q. One goal -- maybe there's -- try and make a list of multiple goals.
One goal is to actually cure incontinence or to improve it. You'd say that's one goal of the surgery?
A. Correct.

Page 139

Q. Another goal is to avoid complications; is that fair?
A. Yes, but you can't separate those two goals. They have to go hand in hand. So it's not like one or the other and say, hey, we have 50 percent because we've got a procedure that cured the incontinence but there's major complications.
So that's why I said it has to be efficacious, meaning it works to cure the problem they're treating and at the same time be safe.
Q. So efficacy, safety are two related goals for the treatment of stress urinary incontinence. Is that fair to say?
A. Yeah. It has to be -- from my opinion, it has to be used in the same sentence. Efficacious and safe.
Q. Would you agree that lower -- or shorter surgery and recovery time is also a goal of the treatment of stress urinary incontinence?
A. That would be a much more secondary goal. If I had a procedure that was going to be 100 percent efficacious, 100 percent safe but was a 3-hour surgery, women would go for it because they're all, now, very concerned about safety. It's a long discussion now compared to when I started my

Page 140

career. When I started my career, it was easy. Now it's a much more detailed discussion, usually.
Q. And why do you think that's the case?
A. Because of awareness with the mesh litigation, no question. And the FDA warning was part of it in 2011 and now it's they can't turn on a TV or a newspaper without seeing mesh warnings. So the patients, in my experience, are coming in much more educated and much more wary than they were in the past.
Q. All right. I'm going to ask you about a couple of documents. I think I got the timeline down pretty well here. In fact, this is just -- again, I just do this for my -- when I go to prepare for your examination at another point in time, this helps me. So that's why I do this.
(Exhibits 5, 6 and 7 were marked for identification.)
BY MR. LEWIS:
Q. I want to ask you about a couple of documents, articles really.
MR. KREIS: If you're in a transition here, at the very beginning of this deposition, I thought we had put on the record that this deposition is both for the MDL and cases

Page 141

coming out of the MDL in terms of his general opinions but also the Clinton case from a general ANK-specific opinion standpoint.
MR. LEWIS: Yeah. I guess I -- my understanding is that this depo is -- we've noticed it in Ms. Clinton's case, which is the case that's set to go to trial in January, and that's my understanding.
MR. KREIS: I've got an e-mail back and forth with either yourself or Dustin where you agree with me that -- just like we had this issue that came up earlier in Dr. Zipper's deposition, you guys had a Clinton style and I said, wait a second, this is an MDL general expert deposition and it's going to be used or can be used in Clinton, and I sent you guys an e-mail and made that very point, that this deposition that we're having today -- so we can -- you know, it's basically asking what style should we use. This deposition is a general MDL deposition but it also includes the case-specific for Clinton.
MR. LEWIS: Right.
MR. KREIS: And you said I agree or Dustin said agree. So we're not intending to have a second deposition on Dr. Elliott's general

opinions.
MR. LEWIS: But he's been named in other specific cases.
MR. KREIS: Right. So if he's a case-specific expert in any other individual litigation, then he's going to avail himself to more depositions. But for this purpose, our understanding and our purpose of being here is to both give opinions that are general opinions to be used in the MDL, including any cases that were remanded out of the MDL, and case-specific specific to Clinton, would you agree?
MR. LEWIS: Well, I guess I'm reserving the right to depose him as a general expert in other cases in which he's been named, again, subject to a reciprocal discussion on how experts are treated and deposed in the litigation. So I'm not making a conclusion one way or the other as to future depositions except to say for purposes of this depo, I am taking his deposition as specific causation expert in Clinton's case and as a general expert which I understand that he's also going to testify in Clinton's case. And to the extent that there's some protocol that's worked out about future depositions of general

experts that have been deposed and it works on both sides of that -- you know, our experts and your experts -- then, you know, we'll follow that protocol for purposes of Dr. Elliott.
So I think I'm saying the same thing, but I'm not restricting my ability to depose him any more than you're restricted -- or any less, I guess, than you're restricted to depose our experts.
MR. KREIS: So our understanding coming into this deposition was that this deposition also covered the MDL general deposition. And I know that in your -- the position that you just enunciated sounds like you're limiting him to Clinton only, and that's where the rub is.
MR. LEWIS: Well, I mean, look, we can -- we're not probably going to resolve this. We can discuss that protocol for how to deal with general experts at another time. What I'm saying is is that whatever rule we're going to apply to Dr. Elliott is the rule that we're going to apply to our experts as well. I'm not applying any special rule to Dr. Elliott that restricts my ability to depose him without also limiting your

ability to depose our experts.
MR. KREIS: That's all understood. And I would just point you back to the e-mail that I sent that you agreed to that made this point very clear, that this was supposed to be a general MDL expert deposition and Clinton case-specific, and we had that agreement coming into this deposition and I can pull it up on my iPhone if I need to.
MR. LEWIS: Like I said, I'll honor any agreements that were made to the extent they're clear and then we're going to apply the same rules to Dr. Elliott as we'll apply to, you know, Dr. Carl Klutke, for instance, or someone on our side in that respect. So I guess that's what I'm saying. I just don't want to get tied up and have my deposition of Dr. Elliott in the future restricted but, you know, you guys get to take Dr. Klutke's deposition and do whatever you want. I mean, the same rules are going to apply to experts similar to Dr. Elliott; Dr. Klutke, those types of experts.
MR. KREIS: Let me ask you this. So by way of example, other cases that we have in this litigation in the district of Minnesota, this

deposition is good for those cases? For example, the Bromley case or the Rector (phonetic) case or any of those 10 cases that we have in the district of Minnesota. Those are cases that have trial dates coming up from January all the way through the summer of 2017. And so those are examples of cases that we understand that this deposition covers, his general opinions relating to those type of cases.
MR. LEWIS: Okay. Well, like I said, I'll abide by whatever protocol and agreement that's been previously, you know, stated on our end. I don't have the information in front of us, and so whatever.
MR. KREIS: Okay.
MR. LEWIS: I guess we'll just deal with it that way. I'm sure we'll be able to resolve that.
MR. KREIS: Okay. Thanks, John.
(Exhibit 8 was marked for identification.)
BY MR. LEWIS:
Q. Let me show you, Doctor, what's been marked as Deposition Exhibit 8. I will represent to you that this was cited in your CV as an abstract.

Page 146

A. Correct.
Q. In the upper left-hand corner, it appears to be published by the Journal of Urology in May of 2005. Do you see that?
A. Correct. This is -- this is the supplement for the AUA. So all it is is all the videos or abstracts they're presenting, so it's not a -- it's not a peer-reviewed process.
Q. Sure. So the AUA is American Urological Association --
A. Association meeting, yes, correct.
Q. And when would that meeting have taken place?
A. I don't recall. This is 2005. Usually it's in May -- late April or early May, so this is probably after the meeting.
Q. And you see here that V496, that is a brief description of what, a presentation that you made?
A. It's a video. I'm assuming. "V" almost always means that we presented something in a video session. And so we present this -- or excuse me, we submit in October of the year prior and it gets accepted and then we present it. So this is -- this is representing our work from October. And then -- so to do a video, this is data that we did probably four months prior,

Page 147

because it takes time to prepare it, submit it and that. Again, I'm assuming that's what the video is.
Q. Is this something that -- did you attend the AUA in 2005, to the best of your knowledge? Would you have attended a video presentation that you did?
A. Yeah, I would assume I would. I don't recall the 2005 meeting at all, but I would assume I would be there. I very, very rarely ever miss. I think I missed once all these years.
Q. Does the fact that this is presented by video, does that mean that you were there live and presented by video to a group of physicians or what does that actually mean?
A. That you submit -- you either have three different ways of presenting data at the AUA: A poster, which is a typed-up poster of your data; a podium presentation, which is slides; or a video presentation.
The video presentation is the lowest bar of data. It's basically how we do it type of a thing, so -- or complications or something like that. It's a surgical technique thing. And so that's what this would have been submitted to.

Page 148

And then I don't go up -- it's almost always the residents. That's why I'm saying it's Dr. Hawatmeh, H-A-W-A-T-M-E-H, who did the video with me and he would be the one to go up front, though I would be in attendance, or at least I would fully expect I would be there.
Q. And you see that this was presented in 2005 at some point in time related to the ObTape sling, correct?
A. That is correct, yes.
Q. Did you tell people at this meeting that you had stopped using ObTape?
A. I don't know. I don't recall. This is not I forum when you're -- you're not -- this is not a discussion forum. This is present a video; thank you; next. So I don't recall. I don't recall if I did any speaking at all on this.
Q. But you would have -- you would have known that this was going to be presented at the meeting?
A. Correct.
Q. And if you had some kind of a concern about the safety of ObTape at this point in time, why wouldn't you have, you know, pulled this down?
A. Well, we don't have the -- once we submit --

Page 149

we submit this in October of the year prior, so six months, eight months prior, which represents data that we collected four months prior to that, probably when we did the video because it takes that long to do th editing and everything. So this is representing, let's just say at the latest, June of '04. And so we don't have the ability to pull -- not -- or retract it. And we don't have the ability to edit this either once it's submitted to the AUA.
Q. You can't call the folks at the AUA and say, hey, this product is -- I'm sorry, I've learned that this product is not safe and I don't really want my name associated with this presentation? You can't do that?
A. We don't have the ability, no. It's submitted and it's gone so that it -- and then it goes a part of the AUA record at that point in time. So there's no editing. You don't have to show up to the meeting, but it's going to be played whether you're there or not. This is different than a poster or a -- then that data is dynamic because you can change it up until the day before, especially the podium. The posters you can't as much.

Page 150

Q. Sure. I mean, maybe you can't change a video but I mean, you certainly could have contacted somebody at the AUA and said, look, I don't support the use of this product any longer. I mean, there was nothing preventing you from writing a letter to the people running the conference and saying, I don't support the use of this product; let's put a little tag line on it?
A. Well, there's nobody to do that to. And also I don't know what was said during this meeting. Dr. Hawatmeh was up front and he could have said, we don't do it anymore; there was a problem. I don't recall. I mean, I don't remember what was done then. Clearly we had stopped using the product by then.
Q. But you were still presenting on the surgical technique to peers, right?
A. Yes. And so was Gona (phonetic). He was presenting on it too.
Yeah, it was presented. But, again, this is representation from really June of '04, five or six months into my using it, when we were very much favorable. I would completely agree with you if this were a poster and definitely a podium presentation because that you can state up

Page 151

in front, and I've done that. But this is set.
Q. Okay. But at least, to the best of your recollection, you don't recall seeking to take any steps -- regardless of what the procedures are, you don't recall affirmatively seeking to take steps to tell anyone at this meeting or associated with this meeting that you don't use ObTape any longer?
A. Again, I don't recall what happened at that -- what happened during the presentation. And we do say we had successful outcomes, short-term outcomes. That we do state.
Q. Sure.
A. But other than that, I don't recall.
Q. I guess if I'm reading this, I'm not seeing that there's a problem in your practice with ObTape. If I'm reading this, V496 in Exhibit 8, I'm personally -- there's nothing here that would tell me that there's a problem with your use of ObTape?
A. You are 100 percent, and that is the terrifying aspect of this. The complications rolled in after we did this video.
But you are correct. Eyeballing this here, there is nothing other than I say it's

Page 152

short-term follow-up, but we were successful in short term.
Q. And I've done a pretty good search of our document database, and I have e-mails. That's how I got that e-mail address before. And I'm not seeing an e-mail from you to Mentor saying I've got a problem with this product.
A. It was verbal discussion with Chris Sellwood over lunch. I don't recall sending an e-mail saying I'm not going to. I talked to Chris Sellwood.
Q. Did you ever -- do you know what -- you obviously know what an Institutional Review Board is, right?
A. Correct.
Q. An Institutional Review Board is a board of individuals at a medical institution that is responsible for allowing a physician at that medical institution to perform a clinical study, among other things, right?
A. That is one of the roles, to maintain proper ethics, protect patients, yes, and to approve studies, yes.
Q. And when you have published your data related to patients, you have had -- at the Mayo Clinic,

Page 153

you have had to get Institutional Review Board approval; is that correct?
A. Now we do. We didn't used to have to do that. When I was a resident and a fellow and in the early part of my career, you didn't have to. That became a very strong, very much enforced rule over time. So yes.
Q. When? What do you think, roughly?
A. That's a good question. I don't recall. It was an evolution of what the rules became. We used to -- they said -- we used to be able just to do any data search we wanted in the records, no problem. Then they said, no, you've got to get approval before you do that. Then they said you've got to have approval before you do anything. And so it became much more strict over time.
Now we can't do anything without having an IRB. I've got an idea for a study, I've got to get an IRB to pursue it any further. Then it has to be approved, which becomes a very stringent process. But during my residency, it didn't exist at all.
Q. And one of the reasons that IRB, Institutional Review Board, approval is necessary

Page 154

to publish data on your cohorts is to protect patient confidentiality; is that correct?
A. Confidentiality and to assure ethical study practices.
Q. What do you mean by "ethical study practices"?
A. Meaning, as a grotesque example, if somebody wants to inject TB in individuals to find out if medications work, okay, it's unethical. You can't do that. And so they will review your study, looking at multiple different factors. I mean, it's like a ten-page process we have to go through to get a study approved, and they're looking at many things: Patient protection, patient confidentiality, what's going to happen with the results, are you going to publish this, what journals are you going to publish this? And it's a long, drawn-out process.
Q. Would you agree that Institutional Review Board approval is also present and required to ensure scientific integrity?
A. Well, I guess I don't know what you mean by "scientific integrity". They don't have the ability to review studies and say, is the researcher being honest with the data. That's

Page 155

not -- they don't have that ability. I could -- you would never do this; you would lose your job -- but you could tell them, here are the results; everything is fine. And they don't have a way of looking at that. Or the opposite, something like that.
They also are screening is their financial bias in the study, those type of things.
So, again, there's multiple things. But they -- they -- scientific fraud or scientific integrity cannot be guaranteed by the IRB process.
Q. Is it something that's looked at? I mean, if they notice something --
A. Well -- I'm sorry. I keep interrupting you.
Q. That's all right.
A. Yes, if they notice something, but that's not part of the -- they would have no ability to notice an indiscretion. They wouldn't have that ability to do that.
Q. Unless it's obvious from the submission itself?
A. Unless it's obvious from the submission itself, then they would.
Q. So with respect to your opinions formed in this litigation related to ObTape, you have not

Page 156

subjected your methodology that you've used to Institutional Review Board approval at the Mayo Clinic, have you?
A. I'm not following your question. I'm sorry.
Q. Sure. I mean, you've obviously published -- it's not a journal, but I mean, you've published your results -- or at least you've talked about your results with Mentor's -- with the Mentor ObTape patients in your reports and also other opinions that you've formed in this case. You haven't subjected -- your work in this litigation related to ObTape, you haven't subjected that to Mayo Clinic IRB review, have you?
A. No, because I'm not performing a study. This would be just a retrospective -- retrospectively -- prospectively gather, retrospectively reviewed, but it's not going to go for a publication, so that has not gone through IRB. If I were going to publish the data, then I would have to do it.
Q. Is there anything preventing you from subjecting the work that you're doing in the ObTape litigation or other mesh litigation to IRB review? Is there anything preventing you from that?

Page 157

A. Again, I'm not following your question. I'm not doing any research or studies -- produced any studies. If the data that I have gathered of my personal experience with patients, if I'm going to submit that to a journal, then yes, we would. And I've done that with the mesh sling because we wrote up a paper. I think Clinton was the senior author on that -- Marissa Clinton and Leitner and then myself, where we talked about mesh sling complications. That data had to go through IRB to be approved.
Q. But that hasn't been done with respect to your work in the ObTape litigation; is that fair to say? You have not sought IRB approval or IRB review at the Mayo Clinic for your work in the ObTape litigation?
A. Yes, because I'm not publishing anything. If I were to publish, I would have to, yes.
Q. And is it also fair to say that you have not subjected your work in other mesh litigation to Mayo Clinic IRB review or approval?
A. Well, again, the closest would be our mesh sling data that we did get an IRB approval for, so the TVTs were included in there, among others. So they're included in there.

Page 158

But only if I'm going to be submitting it to a journal, publishing it somehow, that has to go through IRB. And, again, I have not done that, so it has not been done.
Q. Okay. Let me ask you just a few questions about Ms. Clinton.
In your specific expert report, Exhibit 3, you talk about a concept of differential diagnosis. Do you recall that?
A. Yes.
Q. That's on page 8. And in your report on page 8, you list -- and I guess it's on page 8 and 9 -- you list, I guess, potential causes of Ms. Clinton's injuries that you ruled out as part of your differential diagnosis; is that correct?
A. These are some, a representative of the differential diagnosis that I included. It's not meant to be a comprehensive but just an example of the ideologies that I go through when I evaluate any patient, regardless if it's litigation or not.
Q. So how do I find what your -- what you ruled out in Ms. Clinton's specific case? Let me ask you this. Let me back up. Strike that.
Did you do a differential diagnosis as part of your specific causation testimony in

Page 159

and Andrea Clinton's case?
A. Yes.
Q. Okay. Where do I get the list of things that you ruled out as part of the specific differential diagnosis that you did in Ms. Clinton's case?
A. Well, we have a partial list here of some 25 things on page 8, extending into 9. The comprehensive list won't exist because that will include everything, including tuberculosis, colicystitis, cardiac issues, angina. But very rapidly somebody who does this all the time can eliminate those. So the comprehensive list is going to be in the thousands, literally.
This is more -- the list I provided to you is a more specific but not comprehensive list of the various different processes that I would consider more seriously.
Q. Did you review Ms. Clinton's medical records as part of your work in this case?
A. Yes. There were over 3,000 pages and I reviewed them.
Q. Okay. Did you see in the medical records occasions where physicians attributed her problems to things other than the ObTape?
A. In reviewing all of her records and in

Page 160

reviewing specifically ID and general surgeons who were unaware that she had an ObTape sling in, yes, their differential diagnosis was different but, again, they were unaware that she had that sling in place.
So yes, by all means, I agree with you. That's what I think is the sad part, which delayed her diagnoses, because buttock abscesses, necrotizing fasciitis was known but it was not known to those physicians.
Q. But I guess my point is is that did you review and identify, from the medical records in Ms. Clinton's case, specific potential causes of her complications that were identified by those treating physicians? Did you list them out somewhere?
A. I don't believe I listed them out, per se, because some of them were not within the realm of possibility; i.e., a bug bite on the contralateral buttocks, you know, a mosquito bite, that's not going to cause contralateral groin abscesses and necrotizing fasciitis. So I did not include it because it wasn't within the realm of possibility, okay? We have a polymicrobial infection, bug bites will cause a type 2 necrotizing fasciitis.

Page 161

She had type 1.
Anything like a brown recluse spider, that will cause a tissue necrosis, okay? It will not cause the infectious process. Again, if anything, that would cause a secondary type 2 necrotizing fasciitis. She had type 1.
Things like dental caries, okay? That can cause a polymicrobial infection. But to the best of my knowledge, dental caries, abscesses, will cause local infections: Head/neck fasciitis, which has been described, but she did not have that.
So those things I did not include in there because they are beyond the realm of medical possibility. I tried to limit it to the most likely, most logical, most scientific basis.
Q. Okay. So do you believe that in -- on pages 8 and 9 of Exhibit 3, you have identified the medically possible alternative causes for the complications suffered by Andrea Clinton and then ruled them out?
A. Well, we'd have to go through them one by one. Endometriosis, no, that's not going to cause an abscess. That's not going to cause a necrotizing fasciitis.

Page 162

Gynecologic malignancies, no evidence of that. That's not going to cause necrotizing fasciitis.

Pelvic congestion syndrome, that's a vascular. It causes pain. It doesn't cause infection.

Pelvic inflammatory disease, that's an ovarian -- or a fallopian tube problem. It's not in her.

Tubo-ovarian abscess is a variant of pelvic inflammatory disease. She doesn't have that.

Endocervical causes is along the lines of malignancies. That's not going to do it.

Pelvic adhesions, no evidence of pelvic adhesion disease.

Uterine leiomyomas, that's a benign process. Does not cause infection.

Dysmenorrhea is a uterine problem. It's not going to cause infections.

Adnexal cysts, same thing.

Ectopic pregnancy, no evidence of pregnancies.

Gynecologic skin disorders, lichen sclerosus would be one of those. She doesn't have

Page 163

that.

Mucosal atrophy, at on her age group, there's no reason to suspect. My physical exam said no.

And I can go through the whole list if you want. It's going to take a long time, but I don't mind doing it.

Q. And I guess this is -- my question was a little bit different.

A. Okay.

Q. I'm really looking for -- I need to understand the list of -- not things that aren't medically possible, but the list of medically possible alternative causes for the complications that Andrea Clinton suffered from that you have ruled out.

A. Okay. Specifically to that, as a physician who has dealt with necrotizing fasciitis as a medical student and as a staff, who's used to dealing with Fournier's gangrene which is a subset of necrotizing fasciitis, the ideology of her infections that I have ruled out -- I have ruled out the bug bites. I have ruled out penetrating trauma. I've ruled out trauma. I've ruled out -- off the top of my head, that's the only thing I

Page 164

can think of I've ruled out because this is a situation, based upon my experience as a surgeon in a high-volume center who understands the complications and have treated the complications of ObTape, who has dealt with buttock abscesses in patients -- fortunately none of mine developed necrotizing fasciitis -- I have reviewed the medical literature, I've talked to my colleagues in the GYN department and at national and international meetings, then reviewed the literature -- the medical records on Ms. Clinton, this is due to ObTape.

Q. Have you identified for me all of the medically possible alternative causes other than ObTape that you believe you have ruled out for purposes of your specific causation opinions in Ms. Clinton's case?

A. Well, off the top of my head, I gave you a decent list. There's going to be more.

IV drug abuse ruled out.

Q. Well, and this is --

A. No. That's actually a very good question.

Rectal pathology, which you can have as a cause of Fournier's, she doesn't have.

Urethral diverticulum or urethral

Page 165

strictures she does not have.

And so you rule out those big things and then you're only left with ObTape. So if there's something else, I'd be happy to discuss it. But it looks like a duck, it quacks like a duck, everything pointing towards it, I don't have to go looking for a zebra. But I did look for a zebra as far as the bug bites, brown recluse spider -- or mosquito I should have said first, or idiopathic in an immuno-stable person is unheard of.

Or the dental caries too. That's the other one. Ruled that out.

Q. Why did you rule out the dental injuries?

A. Because she has no -- I will be perfectly willing to be corrected. Every single case that I know of of a tooth abscess causes local head and neck fasciitis and devastating consequences from that. We have no evidence of this being a metastatic, so to speak, seating into the groin because we have no primary. She had a tooth infection but we have no local infection spreading to that. She never developed necrotizing fasciitis of the head and neck, so it doesn't fit. And she had no positive blood cultures, okay? The

Page 166

only way for an infection to get down to the groin would be a positive blood culture. Blood cultures are typically going to be held off until you have -- or excuse me, the antibodies are going to be held off until you do the blood cultures, and so I have no evidence of a positive blood culture.

And when I consider this, if she had a devastating head and neck fasciitis and she had a blood culture that was positive, then by all means I'd reconsider. But see, she didn't have that. So I have to have everything fit. It has to be very logical.

(Exhibit 9 was marked for identification.)

BY MR. LEWIS:

Q. I'm it going to show you what's been marked as deposition Exhibit 9. Exhibit 9 is an article from 2007, lead author, Benassi, B-E-N-A-S-S-I, titled "Abscess formation at the ischiorectal fossa 7 months after the application of a synthetic transobturator sling for stress urinary incontinence in a type II diabetic woman."

Doctor, are you familiar with this article?

A. I don't recall it, per se. I may have

Page 167

reviewed it, but I just don't recall it. The article -- that's what I'm trying to find out is what type of sling they put in.

Q. If we go to the third page of this article -- of this three-page article.

A. And if it were a TVT or TVT-O, I reviewed them but did not put them into the reliance list.

Q. The second paragraph down in the left-hand column of page 3.

A. Monarc sling.

Q. So do you understand that the Monarc sling is a macroporous monofilament polypropylene used in the transobturator technique?

A. It is a macroporous when you follow the Amid system, which is archaic. No one follows it anymore. So it is a microporous when we follow the modern nomenclature.

But I'll agree with you it's larger pores than seen with the ObTape.

Q. And did you use the Monarc sling as part of your practice for a short period of time?

A. Correct.

Q. Did you have infections and erosions with Monarc?

A. I had dyspareunia, sulcus injury. I do not

Page 168

recall if I had any mesh exposure with it.

Q. Go to the paragraph that starts, "Studies have shown".

A. Okay. I'm there.

Q. "Studies have shown" it says, "that meshes of this kind", meaning greater than 75 microns which is what -- the pore size, which is the paragraph before, "carry a lower incidence of erosion due to their larger pore size but make the sling more difficult to remove because the larger pores facilitate the migration of macrophages and leukocytes."

Do you see that sentence?

A. Yes, I do.

Q. Do you agree with it?

A. No.

Q. Why not?

A. Because it's not difficult to get out because of the migration of macrophages and leukocytes. It's more difficult to get out because of the fibrosis. It anchors it in and it's very difficult to get out.

So I agree it's difficult to get out but not by the reasons they say.

Q. And in this case -- you can take some time

Page 169

reporting -- reviewing it, but it's -- the title of it indicates that this individual suffered an abscess seven months after implantation of the Monarc sling through the transobturator route and they theorize about the potential causes in next sentence that I'm going to read to you.

A. I -- you know, that's why I don't use mesh slings, period. So I agree with their conclusion and it was a delayed presentation which I agree with because of the biofilm, et cetera. So I have no problem with this, and that's one of the reasons I stopped using the sling.

Q. Sure. It says, "in our case, the possible causes of erosion and infection could be due to: Rejection of the sling material by the surrounding tissue."

Do you agree that that is a possible cause of erosion and infection in any sling?

A. Well, rejection -- this is -- this does not have DNA associated with it. Rejection -- the true medical definition of rejection is the body views it as non-self, like a kidney transplant. So it is -- it does not integrate, and subsequently causes reaction and inflammation and potentially infection. So I just have trouble

Page 170

with the "rejection" term. I don't think that's a good choice of terms.
Q. What would you use in instead?
A. I would say failure to integrate within the surrounding tissues, causing, you know, scarring and things like that.
So this is a semantics difference. This paper was way back in '07. That's the dark ages of all of our mesh understanding. So I don't fault them for it. It's just not the best term for it because, again, if you talk to most physicians, rejection is an immunologic response, which you don't have that with meshes.
But I agree with their conclusion. Just not to the logic of how they got that point.
Q. So a host response to the sling material could be a possible cause of erosion and infection?
A. Then I would agree with that wording.
Q. Okay. Then number 2, "a higher risk of infection in a patient suffering from diabetes mellitis," if I said that correctly.
A. Yeah. That's --
Q. Do you agree with that?
A. The data will be all over the chart on that.

Page 171

And so diabetes and immunocompromised state due to diabetes will most likely increase the risk of the body's inability to fight off the infection.
So I don't agree or disagree, but you can pull papers out that say it either way. I don't have a problem with it, let's put it that way.
Q. All right. And then thirdly, "Sling placement resulting in too much stretch on the vaginal wall."
Do you agree with that?
A. Yes. Yes, I do.
Q. And then they go on to say, "In conclusion, we can say that infectious complications are possible after transobturator sling procedures."
Do you agree with that?
A. Yes, I do.
Q. All slings, right?
A. No. Disagree.
Q. Not possible with all slings?
A. No. When we're using -- you do not see this vaginal complications -- they say infectious complications. I'll modify what I'm saying.
They're just saying infectious complications can occur after transobturator

Page 172

slings. You can have that. You can reduce it tremendously. We have had zero in our nearly 100 of transobturator autologous. We have no foreign bodies in there.
Q. So --
A. But it can occur.
Q. I'm sorry to interrupt. Let me ask you if you agree with this statement because I think this is what they mean, but -- because this is before your autologous transobturator usage.
In conclusion, infectious complications are possible after transobturator synthetic sling procedures. Would you agree with that statement?
A. Yes, I do. That modification I agree with, sure.
Q. And would you agree that patients should be informed about the risks of erosion and infection and be warned that the appearance of pain and foul-smelling vaginal discharge may be the first symptom of subsequent and more severe infectious complications? Do you agree with that statement?
A. Yes and no. The more severe infections are going to happen when you're not getting that because when you have a vaginal erosion -- or

Page 173

vaginal extrusion, there's a chance for pus to get out, so the only treatment for abscess is to drain it. And so -- but with this, if you have a vaginal discharge, yes, that needs to be reported to your doctor, but absence of vaginal discharge does not exclude infection.
Q. And, again, I know this is just a case report. There are limitations on a case report, fair to say, as far as scientific rank versus a randomized control trial and a case report. There are differences in those two types of publications.
A. There are differences. Its use still can be very helpful.
Q. Okay. You would agree with me that synthetic slings with pores greater than 75 microns can cause abscesses or be responsible or associated with the development of abscesses in patients being treated with stress urinary incontinence?
A. My angle is is all meshes placed in the vagina are wrong and increase the risk for infection. So by stating that, yes, the larger porous can have -- they do have an increased risk for infection. The smaller pore size increases that.

Page 174

Q. So would you agree with me that if Ms. Clinton had a Monarc sling instead of an ObTape sling, she might have had the same result?
MR. KREIS: Object to form.
BY MR. LEWIS:
Q. She could have had the same result?
MR. KREIS: Object to form.
THE WITNESS: At a much less risk frequency, yes.
BY MR. LEWIS:
Q. Sure.
A. All slings that are made of meshes have increased risk for infections, but not all slings are created equal.
And so the Monarc has that risk. There is one case report, versus ObTape having many case reports. But yes, it is a lesser risk with ObTape -- excuse me, Monarc, but can still can occur. I agree with you.
Q. So I just want to make sure I get squared away with the answer to my question.
So if in just Ms. Clinton's case, the only thing you change is a Monarc versus an ObTape, she could have had this very same outcome?
MR. KREIS: Object to form.

Page 175

THE WITNESS: With a much less risk of it, less frequency.
BY MR. LEWIS:
Q. But the answer would be yes?
MR. KREIS: Object to form.
THE WITNESS: Just as I answered, with a much less frequency, it could have occurred.
BY MR. LEWIS:
Q. Okay. But in her specific case. This is one time -- you know, it's Ms. Clinton's one time. She's not a percentage. She's a one-time thing. If Ms. Clinton's case, if she would have had a Monarc instead of an ObTape, it's possible she could have had the same outcome, correct?
MR. KREIS: Object to form.
THE WITNESS: As I stated, I'm very careful with what I'm saying. All slings have increased risk for infection. She could have had a Monarc and she could have had it, but the odds of it occurring are much less likely.
BY MR. LEWIS:
Q. But it still could have occurred with Ms. Clinton in her case, her complications, if she had had a Monarc, correct?

Page 176

MR. KREIS: Object to form, asked and answered.
THE WITNESS: At a much less frequency with the Monarc compared to the ObTape.
BY MR. LEWIS:
Q. In your opinion?
A. No. My opinion and the medical literature support that.
Q. You haven't done any studies to compare the risk of infection or abscesses in ObTape versus other slings yourself? You haven't done any independent Dr. Elliott-spearheaded studies that have been published or peer reviewed or presented to demonstrate the relative frequency of infections and abscesses between ObTape and other slings?
A. I have not conducted a formal study. I've only done an informal study of my ObTape experience versus all the other slings, where all the other slings, so roughly 1,000, I have zero incidents of abscess and with ObTape's 105, I had three. That was not published. I'm relying on the results of others. Boyles, et al., did a comparative study in metaanalysis. So I'm relying on published of other people's data.

Page 177

Q. Not your own study, correct?
A. As I stated that already.
Q. Now, you know that there have been other physicians who have had different and much more successful experience with their patient populations than you have?
MR. KREIS: Object to form.
BY MR. LEWIS:
Q. Correct?
A. I would have to see that data.
Q. Have you looked at the published data from physicians who have reported on their outcomes with ObTape?
A. Yes, I have. Like Juma, et al., a paid study by a Mentor, showing on short term, less complications.
Q. Two years, that's short term?
A. Absolutely. Because this is a permanent implant so we have to talk about the life of the patient, because remember my one patient seven years later came back with a mesh -- an ObTape mesh extrusion. So yeah, that was a short-term study. We'd need to full pull that out because not all patients were followed for two years.
But I am unaware of any independent

Page 178

non-industry-supported study with long-term results that show a good outcome.
Q. When you say "industry reported", I mean, you understand that Dr. Juma's study was peer reviewed, right?
A. Correct.
Q. And just because a study is funded doesn't mean that it's biased, does it?
A. It doesn't mean that it's biased, but articles out there showing that there is the potential for bias. If there weren't the potential for bias, journals and otherwise would not require us to state is it funded or not. If there were no bias, no one would care. But we know that bias is introduced. Therefore, journals require us to say it. And every talk we give now we have to state is there industry funding or not.
Q. And why is that? What's the potential for bias?
A. There is always the potential for bias if money is involved, whoever is funding it. There is a study -- I will not be able to give you the name. I can't recall it. I don't know if it's my report or not, but it's in my reliance list, showing that if a company funds a study -- this

Page 179

was a medication study -- there is more likely going to be a 75 percent chance of positive outcomes for that product versus a non-industry.
So I'm not saying all industry-funded studies are bad, by no means. It raises the potential for it. That's why we have to document that.
Q. Let me just ask you about this last document.
(Exhibit 10 was marked for identification.)
BY MR. LEWIS:
Q. I show you what's been marked as Deposition Exhibit 10. Do you recognize this article?
A. Yes. This is our very first patient or autologous transobturator so we're -- this is the video for it.
Q. And by the way, when you do a surgery using autologous transobturator midurethral sling placement, you get paid for that, correct?
A. No.
Q. You get compensated?
A. No, I do not.
Q. The clinic does?
A. Yeah. I'm paid salary, so I don't get more money if I do or do not do a case. I technically

Page 180

make more money if I don't operate because I don't have to work.
Q. Fair enough.
In the conclusion of this article, you indicate that based on short-term, this autologous mid-urethral sling procedure seems to be feasible and is effective in the short term?
A. Correct. The purpose of this study -- it's a feasibility study -- is can it technically be done. We're not touting it should be done, but we're saying it can be done.
Q. And you indicate that it may become a suitable option for patients and surgeons concerned with potential mesh complications, right?
A. That is correct.
Q. Because you knew at this point in time that there was -- that patients were being impacted by some of the media attention given to mesh complications and they were asking for other options, correct?
MR. KREIS: Object to form.
THE WITNESS: No. I was aware very much. Anything after 2011 is when we saw a spike in patient awareness, so yes, I was aware of that.

Page 181

BY MR. LEWIS:
Q. And at this time, you -- as far as you know, other than someone in London, you were the only person before me autologous transobturator technique surgeries, correct?
A. This was, as far as we know, the world's first procedure like this, yes.
Q. And at this point in time in 2014, you were retained as an expert in litigation involving mesh complications, correct?
A. That is correct.
Q. And you don't disclose in this article, do you, that you are a paid consultant for plaintiff lawyers in mesh litigation, correct?
MR. KREIS: Object to form.
THE WITNESS: No, we do not because we were not -- we're not required to, nor does it have an impact upon our outcome.
BY MR. LEWIS:
Q. Why wouldn't it have an impact on your outcome?
A. Because I've been anti-mesh for a long time and stated it before this litigation process. That's how I was contacted, because I had the statements for Public Citizen, newspaper

Page 182

publications, others being against the complications that are -- or against meshes, okay? So my opinion has not changed. It's been strengthened by this. So there's not impact. There's not change in my opinion.
Q. I mean, I'm reading this. I think I'm getting some objective viewpoint here from Dr. Elliott and, in fact, at this point in time, you're receiving money from plaintiff lawyers to testify against manufacturers of mesh, right?
MR. KREIS: Object to form, argumentative.
THE WITNESS: Yeah. This is -- as we state in there, this may become a suitable option for patients and surgeons concerned about potential mesh. That does not impact upon my income at my intuition, nor my involvement in this. We're just saying this is a potential option.
BY MR. LEWIS:
Q. I understand, but you're saying -- look at this second page. "Conflicts of interest," what does that mean to you?
A. That means am I getting money from industry to do this? No. That's what that means.

Page 183

Q. Well, you're getting money from somebody at this point in time, aren't you?
A. Yes, but --
MR. KREIS: Object to form.
THE WITNESS: But that has nothing to do with this conflict of interest as they're asking it. This is from industry, which there are no -- I'm not getting paid by any outside sources to do this study.
BY MR. LEWIS:
Q. Well, conflict of interest, isn't that -- does this -- is there the potential that -- this person publishing this science, is there the potential that this person is receiving some financial benefit for saying the scientific things that they're purporting to say in this article. Isn't that really what conflict of interest is all about?
MR. KREIS: Object to form.
THE WITNESS: Well, no, because that is not pertinent for this. This is an option for patients who are concerned about mesh, okay? So I'm not coming out here -- nowhere in here do I state anything negative against mesh, other than there's patient concerns and known complications,

Page 184

which is in the literature. I am following all the rules. This has no financial bearing upon me. I don't get a penny more by doing this paper or treating these patients.
BY MR. LEWIS:
Q. Well, let's think about that for a minute. So if -- if this transobturator autologous sling procedure catches on in the United States and people start flooding into the Mayo Clinic because you folks are the only ones who do it, you've got to agree with me that there would be some financial benefit through your salary or to the Mayo Clinic?
A. I get --
MR. KREIS: Object to form.
THE WITNESS: I get nothing. I am pure salary. I don't get a penny more if I do a procedure or not.
BY MR. LEWIS:
Q. Yeah, but you get raises every year, don't you?
MR. KREIS: Object to form.
THE WITNESS: We get cost-of-living raises only.
BY MR. LEWIS:

Page 185

Q. No merits raises?
A. None. None at Mayo since 1920 when the Mayo brothers instituted that. So I don't get -- so it eliminates financial incentive. So I have none. By me doing this, I actually potentially increase my workload, which has not panned out, by any means. We are still publishing on this and warning that we don't have the long-term results yet, so we have to pan that out. So we're not out there touting it. I am not like Delorum (phonetic) or Ulmsten who gets $1.2 million or more for doing something depending upon the results. I don't get anything for this.
Q. Well, you get paid by plaintiff lawyers who are suing mesh manufacturers to say that mesh is bad?
MR. KREIS: Object to form.
THE WITNESS: No. I am being paid for my opinion that was established prior to any involvement in the litigation process. They would not have come to me had I not already had an opinion, which is -- clearly if you look up that comment, that is prior to any contact with any lawyer. So in my opinion, if you look at that and you look at now, if anything, that's become more

firm because I know more. So, again, it has not changed.
BY MR. LEWIS:
Q. Let me ask you this: Of the 75 IMEs that plaintiff lawyers have had you do patients in their litigation, how many of those did you call back and say, you know what? This was not caused by the mesh?
A. I can't give you an exact number because I don't recall, but there have been some. I tell them this patient is malingering.
We had a drug-abusing psycho three or four weeks ago, not associated with this one, that I said, this person is nuts; I can't give you that.
Also I have rejected many once I reviewed their records saying, this is not legitimate. If it's not legitimate, I don't even do an IME. Then once I do the IME, if I feel they're nuts, I tell them. And I have refused to give testimony on certain one of those because I said, I'm not sticking my neck out for that. So every one that I've given testimony on there has been legitimacy to it, bar none.
MR. LEWIS: Give me two minutes.

MR. KREIS: I've got a couple of questions. Not much.
MR. LEWIS: Okay. Well, why don't you ask your questions now and I think I'm pretty much wrapped up. And give me a chance to ask a question or two if I missed it.
MR. KREIS: Of course.

EXAMINATION

BY MR. KREIS:
Q. Dr. Elliott, you were asked questions earlier about the instructions for use, or what they call the PIDs in this litigation. Do you recall that testimony?
A. Yes, I do.
Q. And you testified that the sales rep, Mr. Smallwood [sic] had provided you a PIDs --
MR. LEWIS: Sellwood.
BY MR. KREIS:
Q. -- Sellwood had provided you a PIDs prior to your first implantation, correct?
A. That is correct. On the introduction of this idea, he provided me with the PID, the instructions for use, surgical video, and I don't

recall what else.
Q. And that was in the context of the Mentor sales representatives trying to gain your interest in this procedure, correct?
MR. LEWIS: Object to foundation.
THE WITNESS: That is correct. It was -- it was -- well, ultimately their goal was to make me -- want me to do that project. It was an introduction that this is now available -- or will be available.
BY MR. KREIS:
Q. And I think if I'm correct on this factually, you testified that it wasn't that you had reached out to him and said, hey, give me the Mentor ObTape PIDs but rather, it was part of a presentation that he made to you, correct?
A. I mean, I -- we're going a long ways back. I don't recall if I asked for it. What I usually do is ask for all information that you've got, and this is what was presented to me.
Q. Okay. And so at that same period of time, you were provided with a video -- or at least you observed a video that was on his laptop; is that correct?
A. That is correct, yes. A DVD video.

Q. A DVD video. And that was of the transobturator technique?
A. That is correct, using the Mentor -- the ObTape.
Q. And you had indicated earlier that I think this is information that you don't have access to now, but that he also had a packet of information that he reviewed with you, along with the PIDs and along with this video, correct?
A. Again, I can't recall what else he gave me besides that. I don't know if there was manuscripts or whatever. I just don't recall. I do recall getting the big booklet when I went to the meeting in Phoenix.
Q. Okay. And with respect to what you relied on to make this change in your clinical practice, which included starting to implant the ObTape, you relied on Mentor to provide you with thorough information, both with respect to the obturator approach and also any risks associated with their product and the approach, correct?
MR. LEWIS: Object to form.
THE WITNESS: I think it's fair to say with specifically this product -- it varied with other products -- I relied nearly 100 percent

Page 190

upon them and I trusted them.
BY MR. KREIS:
Q. Okay. And you were asked a question about the PIDs, and the PIDs makes reference to there being a very rare risk of various things. Do you remember that testimony?
A. Yes, I do.
Q. And those rare occurrences -- those very rare occurrences include erosion, correct?
A. They say vaginal erosion, which correctly should be called "extrusion". But it's okay at that time to call it erosion, yes.
Q. There's also reference there to infection?
A. Correct.
Q. And at the point in time when you were being presented with this PIDs, was it your impression that that infection dealt with superficial surgical-related infection?
MR. LEWIS: Object to form.
THE WITNESS: Correct. At that point in time, I was aware of the medical literature. I'd wear my own clinical experience. And the superficial skin infection of cellulitis, I remember there was one patient that I had with it that we were able to treat. I remember it very

Page 191

well because a staff pulmonologist's mother, so it's burned in my mind and I have to deal with that. But it was a minor infection treated with antibiotics and it went away.
BY MR. KREIS:
Q. And at this point in time, you would not have known that there would be a significant risk of abscess formation, correct?
MR. LEWIS: Object to form.
THE WITNESS: I was completely unaware. I'd had never heard about it, never heard it in the literature, never seen a patient with it. Never even knew abscess was even possible with these things.
BY MR. KREIS:
Q. And so --
A. In the absence -- sorry to interrupt you, but in the absence of a bowel perforation, like with the TVT or suprapubic sling.
Q. Okay. So both from the standpoint of your being a clinician at the point in time when you received the PIDs and also as an expert in this case, is it your opinion that their reference to "infection" in the PIDs is inadequate based on the information you have now?

Page 192

MR. LEWIS: Object to form and foundation.
THE WITNESS: Wholly misleading, because you have to look at the frame of reference of every doctor in the nation -- well, just to myself, who was aware of the mesh sling issues with TVT and SPARC, which I had already used, that was my frame of reference. I understood infections in that realm. I did not understand nor expect the complications I found in my own patients, like the buttock abscess I mentioned.
Q. And you told this Mentor sales representative about the buttock abscess, correct?
A. I told about each one as they occurred. I also told them about the vaginal extrusions, because remember, very rarely -- I remember a few that I was seeing with the other products. So as these were coming in, I was telling them, hey, we're seeing this thing; this is different.
Q. Did you ever see a change made by Mentor to their PIDs specific to the serious abscess formation risk at any point in time?
MR. LEWIS: Object to form.
THE WITNESS: No. When this was occurring and I was telling Mr. Sellwood -- I

Page 193

don't recall if I told Terri Oto or not or Dave Amerson. Dave Amerson I had very little contact with.
I told them about this. I was somewhat under the impression I was the only one in the world who was experiencing this.
BY MR. KREIS:
Q. Did Mentor ever tell you about conversations they had with, for example, Dr. Kassan (phonetic) in May of 2004 relating to serious infections that he saw with the ObTape?
MR. LEWIS: Hold on a minute. This is an expert deposition, not a factual deposition, number one, and so this has nothing to with any of the questions that I asked this expert. These are all brand-new issues being raised here. So I'm objecting to any examination into these areas. I mean, I'm moving to strike them. This is my deposition. I'm paying for it.
MR. KREIS: I understand.
MR. LEWIS: This isn't a clarification.
MR. KREIS: I understand your clarification.
MR. LEWIS: So how much more of this

do you got?
MR. KREIS: Not much.
MR. LEWIS: Well, I mean, like a question or two.
MR. KREIS: On this topic -- I've got no more questions on this topic if you'll let the doctor answer the question.
MR. LEWIS: Go ahead. But I still object on those bases.
THE WITNESS: I'm sorry. I forgot what the question was.
BY MR. KREIS:
Q. Do you recall if Mentor ever provided you information relating to Dr. Kassan's advising Mentor about the abscess formation that he was seeing in his practice in May of 2004?
A. I don't recall that.
Q. Okay. Did you review Dr. Manian, the infectious disease doctor expert for Ms. Clinton, did you review his expert report?
A. His expert report and his deposition. I've read them.
Q. Okay. And by "expert report", that includes his supplemental expert report, correct?
A. Well, that's a blur in my mind. I saw all

the documents. I can't say which one was on supplemental and which one was on --
MR. LEWIS: Is that referenced in his report?
MR. KREIS: Yes. It's referenced in his supplemental reliance list.
MR. LEWIS: Well, so here's the point on this. I'm reserving my right to ask him questions about this supplemental reliance list. I just got it. It should have been provided, including any questions about Dr. Manian. So I mean, I'm just letting you know. I mean, you can ask all the questions you want, but --
MR. KREIS: You've had -- certainly you've had Dr. Manian's expert, his supplemental expert report. You've got his deposition transcript. We sent you Dr. Elliott's supplemental reliance list.
MR. LEWIS: You just sent it to me. It was not sent with the actual report, and Dr. Manian's information was not included in the original reports of Dr. Elliott and I'm going to reserve my right to strike any reliance on Mr. Manian or I'm going to open this deposition back up so I can fully examine him. I didn't come

here today to prepared to talk about Dr. Manian's opinion because I was wasn't provided -- it's not in the four corners of his report.
But I don't -- I'm objecting to this line of examination. This is stuff that you can get out of him at trial. This isn't related. I didn't ask him anything about Dr. Manian. So I'm prohibiting this line of questioning.
MR. KREIS: I've got very few questions on this. Your objection is understood.
MR. LEWIS: Okay.
MR. KREIS: Let's let this proceed a couple more questions, okay, John?
MR. LEWIS: Okay.
BY MR. KREIS:
Q. Dr. Elliott, you had an opportunity to review Dr. Manian's expert report and his supplemental expert report and his deposition transcripts, correct?
A. Correct.
Q. Okay. You're aware that Dr. Manian holds the opinion that Ms. Clinton suffered an abscess to her left thigh caused by colonization of the material at the time of implant and there was a delay in the presentation due to biofilm

formation, correct?
A. Yes, that's correct.
Q. And would it be accurate that your opinion is that the ObTape caused her thigh abscess in her left leg and her right leg?
MR. LEWIS: Object to form.
THE WITNESS: Correct.
BY MR. KREIS:
Q. Okay. And is it -- and that would be either through an undiagnosed erosion causing the infection to the ObTape, or colonization at the time of the implant, correct?
MR. LEWIS: Object to form.
THE WITNESS: Either or both, correct.
BY MR. KREIS:
Q. In terms of things that you've ruled out, one thing that Mr. Lewis didn't ask you about and I wanted to make sure and clarify for the record, you reviewed the implant operative records, correct?
A. Correct. Dr. Saba's from December of 2005.
Q. 2004?
A. 2004. Excuse me.
Q. And did you rule out any implantation

technique or other issues with respect to Dr. Saba's implant as part of your opinion?
A. I read over his report. It appeared to follow the standard of care. There was no suspicious issues with the report.
Q. Okay. And all of the opinions that you gave today are to a reasonable degree of medical certainty?
MR. LEWIS: Object to form.
THE WITNESS: Correct.
MR. KREIS: I've got no further questions.
MR. LEWIS: I'm just going to reserve my right to further question the witness based on recent information that was provided to us and also any information that's revealed between now and the time of trial.
Otherwise, I have no further questions for the witness. I appreciate your time, Dr. Elliott.
MR. KREIS: Plaintiffs do not waive their objections to any further deposition and do affirmatively object to leaving this deposition open but will take the issue up with counsel at the close of this deposition.

Thank you.
(The deposition was concluded at 1:15 p.m.)

REPORTER'S CERTIFICATE

STATE OF MINNESOTA)
) ss.
COUNTY OF RAMSEY)

I hereby certify that I reported the DEPOSITION OF DANIEL S. ELLIOTT, M.D., on July 24, 2016, in Minneapolis, Minnesota, and that the witness was by me first duly sworn to tell the whole truth;
That the testimony was transcribed by me and is a true record of the testimony of the witness;

That the cost of the original has been charged to the party who noticed the deposition, and that all parties who ordered copies have been charged at the same rate for such copies;
That I am not a relative or employee or attorney or counsel of any of the parties, or a relative or employee of such attorney or counsel;
That I am not financially interested in the action and have no contract with the parties, attorneys, or persons with an interest in the action that affects or has a substantial tendency to affect my impartiality;
That the right to read and sign the deposition by the witness was reserved.

WITNESS MY HAND AND SEAL this 3rd day of August, 2016.

_____
Paula K. Richter, RMR, CRR
Notary Public, Ramsey County, Minnesota
My Commission Expires January 31, 2021

ERRATA SHEET
VERITEXT LEGAL SOLUTIONS
800-567-8658
ASSIGNMENT NO. CS2350044
CASE NAME: Clinton, Andrea Rachelle v. Mentor Worldwide LLC
DATE OF DEPOSITION: 7/24/2016
WITNESS' NAME: Daniel S. Elliott

PAGE/LINE(S)	CHANGE	REASON

_____
Daniel S. Elliott
(Notary not required in California)
SUBSCRIBED AND SWORN TO BEFORE ME THIS _____ DAY OF _____, 2016.

_____
NOTARY PUBLIC
MY COMMISSION EXPIRES _____

Veritext Legal Solutions
290 W. Mt. Pleasant Ave. - Suite 3200
Livingston, New Jersey 07039
Toll Free: 800-227-8440 Fax: 973-629-1287

_____, 2016

To: Douglass A. Kreis, Esq.
Case Name: Clinton, Andrea Rachelle v. Mentor Worldwide LLC
Veritext Reference Number: 2350044
Witness: Daniel S. Elliott Deposition Date: 7/24/2016

Dear Sir:

Enclosed please find a deposition transcript. Please have the witness review the transcript and note any changes or corrections on the included errata sheet, indicating the page, line number, change, and the reason for the change. Have the witness' signature at the bottom of the sheet notarized except in California where they are signing under penalty of perjury and forward the errata sheet back to us at the address shown above.

If the jurat is not returned within thirty days of your receipt of this letter, the reading and signing will be deemed waived.

Sincerely,

Production Department

Encl.
Cc: John Q. Lewis, Esq.

REPORTER'S CERTIFICATE

STATE OF MINNESOTA)
) ss.
COUNTY OF RAMSEY)

I hereby certify that I reported the DEPOSITION OF DANIEL S. ELLIOTT, M.D., on July 24, 2016, in Minneapolis, Minnesota, and that the witness was by me first duly sworn to tell the whole truth;

That the testimony was transcribed by me and is a true record of the testimony of the witness;

That the cost of the original has been charged to the party who noticed the deposition, and that all parties who ordered copies have been charged at the same rate for such copies;

That I am not a relative or employee or attorney or counsel of any of the parties, or a relative or employee of such attorney or counsel;

That I am not financially interested in the action and have no contract with the parties, attorneys, or persons with an interest in the action that affects or has a substantial tendency to affect my impartiality;

That the right to read and sign the deposition by the witness was reserved.

WITNESS MY HAND AND SEAL this 3rd day of August, 2016.

Paula Richter

Paula K. Richter, RMR, CRR
Notary Public, Ramsey County, Minnesota
My Commission Expires January 31, 2021